day when issued.'' 21 CFR 1306.05(a). DEA has repeatedly held that the act of pre-signing a prescription violates the CSA. *See Alvin Darby,* 75 FR 26993, 26999 (2010) (collecting cases). Thus, whether I accept the Government's contention that Respondent issued a prescription when he lacked state authority to do so, or Respondent's assertion that he simply pre-signed a prescription, he still distributed a controlled substance in violation of 21 U.S.C. 841(a)(1). However, the record contains no evidence that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescription.[9]

Sanction

The Government argues that it has ''establishe[d] by a preponderance of the evidence that Respondent's continued registration is inconsistent with the public interest'' and that Respondent has put on ''no evidence that could support a finding that [he] should be entrusted with a . . . registration.'' Req. for Final Agency Action, at 9–10 (citing cases). The Government thus seeks the revocation of Respondent's registration.[10]

Had the Government proved that Respondent materially falsified his application, I would grant the Government's request. The Government, however, has proved only that Respondent committed a single act of issuing a prescription in violation of DEA regulations (whether because he lacked state authority or pre-signed/post-dated the prescription). Moreover, the Government has produced no evidence that the prescription lacked a legitimate medical purpose. *See Dewey C. MacKay,* 75 FR 49956, 49977 (2010) (holding that DEA can revoke a practitioner's registration based on a single act of intentional diversion), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011).

As I have previously held, in determining the appropriate sanction, DEA considers the egregiousness and the scope of the misconduct which has been proved on the record, as well as the need to deter similar misconduct on the part of others. *See Michael S. Moore,* 76 FR 45867, 45868 (2011); *Terese, Inc.,* 76 FR at 46848–49; *Janet L. Thornton,* 73 FR 50354, 50356 (2008).

In *Thornton,* the Government sought the revocation of a physician's registration, based on her having written two controlled substance prescriptions for former neighbors, when her license to practice in that State had been suspended. 73 FR at 50355. The physician, however, was practicing in another State, where she was licensed. *Id.* While the then-Deputy Administrator found that the prescriptions violated federal law because the physician engaged in the unlicensed practice of medicine and were thus issued outside of the usual course of professional practice (which the physician admitted in a state board proceeding), she declined to revoke the physician's registration, noting that there was no evidence that the physician had written the prescriptions ''for other than a legitimate medical purpose.'' *Id.* The Deputy Administrator also noted that a provision of state law created an exemption from the State's licensing requirements for ''occasional consultations or cases'' where a physician was ''lawfully practicing medicine in another state,'' and that while the State Board found that the physician violated the State's Medical Practice Act, the physician's case appeared to be one of first impression. *Id.* at 50356. Based on these circumstances, the Deputy Administrator concluded that the physician's violations did not warrant the revocation or suspension of her registration. *Id.*

Here, while the proven misconduct is limited to a single prescription, I conclude that a period of outright suspension is warranted. In contrast to *Thornton,* where the state law defining what constituted the unauthorized practice of medicine was arguably unclear, the applicable DEA regulations are clear, whether Respondent issued the prescription after his state license was revoked, *see* 21 CFR 1306.03(a), or whether he pre-signed (and post-dated) the prescription. *Id.* 1306.05(a). In either case, the evidence supports a finding that Respondent knowingly dispensed a controlled substance in violation of the Controlled Substances Act. *See* 21 U.S.C. 841(a)(1). Accordingly, I will order that Respondent's registration be suspended outright for a period of six months.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(4), as well as 28 CFR 0.100(b), I order that the DEA Certificate of Registration issued to Hoi Y. Kam, M.D., be, and it hereby is, suspended for a period of six months. This Order is effective November 21, 2013.

Dated: October 9, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013–24627 Filed 10–21–13; 8:45 am]

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[9] The Government also argues that factor one—the recommendation of the state licensing board—supports its proposed sanction of revocation. According to the Government, ''[t]hough his medical license is not revoked, and the allegations underlying action did not involve controlled substances, such action still weighs in favor of revocation.'' Req. for Final Agency Action, at 8 (citing *George Mathew,* 75 FR 66138, 66145 (2010)).

While my decision in *Mathew* noted that the respondent there had been subject to two disciplinary proceedings by the state board, one of the proceedings (which resulted in a summary suspension) was based on the respondent's failure to properly treat emergency room patients and did not involve his prescribing of controlled substances. 75 FR at 66,145. However, at the time of this Agency's proceeding, the State had reinstated Respondent's medical license. *Id.* Accordingly, I placed no weight on that proceeding and relied only on the other proceeding, which sanctioned the respondent for prescribing controlled substances to patients he never physically examined. *Id.* Thus, the Government's reliance on *Mathew* is misplaced.

[10] The Government also argues that Respondent's renewal application should be denied. Req. for Final Agency Action, at 1. However, it is too late for that, as the Government renewed Respondent's registration on April 3, 2012. GX 1.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–6]

Lannett Company, Inc.; Grant of Registration To Import Schedule I Substance

On November 15, 2012, I, the Administrator of the Drug Enforcement Administration, issued a Declaratory Order in the above-captioned matter.[1] Therein, I held that Lannett Company, Incorporated's (hereinafter, Lannett) proposed importation of synthetic dronabinol (THC) in finished dosage form, a schedule I controlled substance, for the purpose of conducting stability and bioequivalency studies to support an Abbreviated New Drug Application (ANDA), constitutes ''scientific, analytical, or research uses'' and is therefore a permissible importation under 21 U.S.C. 952(a)(2)(C). Declaratory Order, at 36. However, I further held that Lannett had not justified that the quantities of the proposed importations (300,000 dosage units) were ''limited quantities'' as required by section 952(a)(2)(C). *Id.* at 35–36. I therefore ordered Lannett to provide justification for the quantities it sought to import. *Id.* at 40. I also held that upon Lannett's ''providing adequate justification for the quantit[ies] of the [proposed] importation[s],'' its ''registration would be consistent with

[1] All citations to the Declaratory Order are to the slip opinion and not to the Order as published here in the Appendix.

the public interest.'' *Id.* (citing 21 U.S.C. 823(a)).[2]

In response, Lannett filed a new application, seeking to import 10,000 dosage units for each of the three dosage strengths for which it intends to file an ANDA.[3] *See* Lannett Company, Inc.'s Response To The Administrator's Declaratory Order of November 15, 2012. Thereafter, the Government objected to Lannett's new proposed quantities, contending that Lannett had not adequately justified them. Government's Request To Have Lannett Company, Inc., Amend Its Import Application To Conform To The Administrator's Declaratory Order of November 15, 2012, at 2. Thereupon, I directed Lannett to file a response to the Government's request. Order (June 12, 2013).

On June 28, 2013, Lannett filed an amended application, explaining that it now needs 7,000 capsules of each dosage strength for which it intends to file an ANDA. Lannett Company, Inc.'s Response to the Administrator's Declaratory Order of June 11, 2013. Neither the Government, nor the firms which objected to Lannett's application, filed a response to the amended application. Having reviewed Lannett's amended application, I conclude that it should be granted.

Order

Pursuant to the authority vested in me by 21 U.S.C. 958(a) and 28 CFR 0.100(b), I order that the application of Lannett Company, Incorporated, for a DEA Certificate of Registration authorizing it to import Tetrahydrocannibinols (Drug Code 7370) for the purpose of conducting research be, and it hereby is, granted. Pursuant to the authority vested in me by 21 U.S.C. 952(a)(2)(C), I further order that a rule be, and it hereby is, issued, authorizing Lannett Company, Incorporated, to import the amounts of Tetrahydrocannibinols set forth in its amended application.[4]

[2] However, I held that Lannett's application for a registration to import THC should be held in abeyance.

[3] Neither of the firms which objected to Lannett's application (Rhodes Technologies and Mallinckrodt) filed a response to its submission. *See* Declaratory Order at n.32.

[4] As stated in the Declaratory Order, the quantities of Tetrahydrocannibinols imported pursuant to this rule may only be used for the purpose of conducting research in support of its ANDA and may not be commercially distributed.

Dated: October 8, 2013.

Michele M. Leonhart,

Administrator.

Appendix

Docket No. 08–6

LANNETT COMPANY, INC.

DECLARATORY ORDER

Introduction

Under the Controlled Substances Import Export Act (hereinafter, ''CSIEA''), a person seeking to lawfully import a schedule I or II controlled substance into the United States must obtain from the Drug Enforcement Administration both a registration as an importer and permission to import the substance. *See* 21 U.S.C. §§ 952(a); 958(a). Under section 952(a), other than in the case of narcotic raw materials, it is unlawful ''to import into the United States'' any schedule I or II controlled substance ''except that such amounts of any controlled substance in schedule I or II . . . that the Attorney General finds to be necessary to provide for the medical, scientific, or legitimate needs of the United States'' may be imported pursuant to ''such regulations as the Attorney General shall prescribe'' if one of three conditions is satisfied. *Id.* § 952(a)(2).

Relevant here are subparagraphs (2)(B) and (2)(C). The former provision authorizes an importation ''[i]n any case in which the Attorney General finds that competition among domestic manufacturers is inadequate and will not be rendered adequate by the registration of additional manufacturers under [21 U.S.C. §] 823.'' *Id.* § 952(a)(2)(B). The latter provision authorizes an importation ''in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses.'' *Id.* § 952(a)(2)(C).

Procedural History

On October 10, 2006, Lannett Company, Inc., of Philadelphia, Pennsylvania (hereinafter, Lannett), applied for a DEA Certificate of Registration authorizing it to import tetrahydrocannabinols (THC), a schedule I controlled substance.[1] ALJ Ex. 1, at 1. Lannett sought to import the THC ''for analytical testing on a formulated product for submission to the U.S. Food and Drug Administration (FDA) for generic product approval.'' *Id.* While Lannett's application is not in the record, according to the affidavit of its Chief Executive Officer, the company sought to import three ''submission batches of . . . finished dronabinol capsules,'' comprised of 100,000 capsules each, which would be tested at both its facility ''and at a clinical laboratory that will conduct bioequivalency testing'' to provide data to support the filing of an Abbreviated New Drug Application (ANDA) with FDA. LX 1, at 6; Tr. 37.[2]

It is undisputed that the dronabinol, which is the subject of Lannett's application, is a schedule I controlled substance. 21 CFR 1308.11(d)(30). However, when synthetic dronabinol in sesame oil is encapsulated in a soft gel capsule, and is an FDA-approved drug, it is a schedule III controlled substance. *Id.* 1308.13(g).

On September 19, 2007, the Deputy Assistant Administrator, Office of Diversion Control, published the Notice of Application. ALJ Ex. 1, at 1. Therein, the Deputy Assistant Administrator specifically noted that ''[p]ursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II and prior to issuing a registration[sic] [3] under 21 U.S.C. 952(a) authorizing the importation of such substances, provide manufacturers holding registrations for the bulk manufacture of the substances an opportunity for a hearing.'' *Id.* (quoting 21 U.S.C. § 958(i)). The Notice of Application then stated that ''[a]ny manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.'' *Id.* at 1–2.

Thereafter, Rhodes Technologies timely requested a hearing on the application, noting that it is registered as a bulk manufacturer of THC and is therefore ''among the category of firms entitled to a hearing on the proposed registration pursuant to 21 CFR 1301.34(a).'' ALJ Ex. 2, at 1–2. Rhodes further explained that it sought ''to be heard on the issue of whether . . . the proposed registration of [Applicant] as an importer of THC . . . is consistent with the applicable legal standards reflected in the DEA regulations at 21 CFR 1301.34(b) and the Controlled Substances Act at 21 U.S.C. §§ 952(a), 958(a), and 823(a).'' *Id.* at 2.

Mallinckrodt, Inc., another registered manufacturer of THC, also filed comments and objections to the application.[4] ALJ Ex. 3,

[1] Lannett also applied for a registration authorizing it to import methylphenidate and morphine, both of which are schedule II controlled substances. ALJ Ex. 1, at 1. Lannett, however, subsequently withdrew its application to import these two substances. ALJ Ex. 7.

[2] According to the affidavit of Lannett's Chief Executive Officer (CEO), the company sought ''to import one (or possible [sic] two) submission batches of . . . approximately 3,000 capsules.'' LX1, at 6. However, at the hearing, its CEO testified that the Company was seeking permission to import (in finished dosage form) three batches of 100,000 units each. Tr. 37.

[3] The notice mistakenly used the word ''registration'' rather than ''regulation.'' *See* 21 U.S.C. § 958(i). Section 952 is not a registration provision; rather it requires that an importer establish that the proposed importation is permissible under one of the various provisions set forth therein. *See* 21 U.S.C. § 952(a).

[4] Mallinckrodt also requested a hearing on Lannett's applications for registrations as an importer of methylphenidate and morphine. ALJ Ex. 3, at 1. As noted above, *see* n.1, on March 18, 2009, Lannett withdrew its applications for registration to import these two controlled substances.

at 1. Mallinckrodt objected on the grounds that: 1) THC has no currently accepted medical use, and that therefore, it ''is not the type of controlled substance that should be imported unless necessary,'' *id.* at 6; 2) that ''a medical substitute [Marinol] readily exists in sufficient supply which is at least as effective and [which] is much less dangerous,'' and that therefore, Lannett's proposed importation of THC is not ''*necessary* to provided for the medical needs of the United States'' under 21 U.S.C. § 952(a), and that by denying Lannett's application, ''DEA can entirely avoid the risk of such international diversion.'' *Id.* at 7.

Thereafter, both Lannett and the Government moved to dismiss the proceeding on the ground that under 21 U.S.C. § 958(i), a third-party manufacturer such as Rhodes is entitled to request a hearing only where the applicant for an import registration is also a bulk manufacturer of the substance. Motion of Lannett to Dismiss and Terminate Proceedings, at 4. Lannett maintained that it is a ''finished dosage form'' manufacturer, and not a ''bulk manufacturer'' of controlled substances, *id.* at 3, and that therefore, ''there is no jurisdictional basis for a hearing in this matter.'' *Id.* at 2.[5] Relying on a **Federal Register** notice in which I directed an Administrative Law Judge to dismiss a hearing which was docketed when several companies sought to challenge an application to import narcotic raw materials because the objecting companies did not bulk manufacture these substances[6], *see* 72 FR 3417[7] (2007), Lannett also contended that while Rhodes and Mallinckrodt are bulk manufacturers of THC, it ''does not seek to import such substances in bulk form.'' Lannett's Mot. to Terminate, at 5.

The Government supported Lannett's motion, arguing that ''under the express terms of section § 958(i), the applicant also must be a bulk manufacturer'' of the controlled substance in order to trigger the right of another bulk manufacturer to challenge the application for an import registration. Gov. Mot. to Dismiss The Hearing Requested By the Intervenors at 3–4. According to the Government, because Lannett ''is not a bulk manufacturer of any of the controlled substances it seeks to import[,] . . . under the plain terms of Section 958(i) and the quoted language from the **Federal Register** decision [72 FR 3417], the interveners do not have the statutory authority to obtain a hearing.'' *Id.* at 4.

On May 28, 2008, the ALJ issued her ruling on the motion to dismiss. *See* Memorandum To Counsel and Ruling on Request for Hearing. Therein, the ALJ noted that ''[n]one of the parties has asserted that Lannett is a current bulk manufacturer, or is attempting to gain registration as a bulk manufacturer'' of THC. *Id.* at 20. Because ''Lannett is not a bulk manufacturer of tetrahydrocannabinols,'' the ALJ concluded that ''the hearing right provided by § 958(i) is not triggered prior to the DEA issuing a registration to Lannett to import tetrahydrocannabinols.'' *Id.*

The ALJ further noted, however, that ''[t]he rulemaking provision of § 958(i) provides manufacturers, who currently hold registrations as bulk manufactures of a Schedule I or II substances, the right to a hearing before the DEA issues a regulation under § 952(a) that authorizes the importation of a substance that those manufacturers are registered to bulk manufacture.'' *Id.* at 21. According to the ALJ, ''[b]y its plain language, this hearing right does not appear to be limited to situations in which the importer of the controlled substance is also a bulk manufacturer.'' *Id.* The ALJ reasoned, however, that ''[n]othing in the language of the statute signals Congress' intention that the rulemaking authorized by this provision be made after formal [on the record] proceedings,'' and that DEA is required to provide only for notice and comment rulemaking pursuant to 5 U.S.C. § 553(c). *Id.*

The ALJ then addressed whether the Objectors had a right to a hearing under 21 CFR 1301.34(a). *See id.* According to the ALJ, ''[p]ursuant to 21 CFR 1301.34(a) current bulk manufacturers of a Schedule I or II controlled substance are entitled to a hearing on an application for registration to import that substance, if the Administrator is acting under the authority of 21 U.S.C. § 952(a)(2)(B).'' *Id.* The ALJ noted that ''Lannett never explicitly asserted in any of its briefs that it was attempting to import any of the substances at issue under [the authority of section] 952(a)(2)(C),'' the provision which authorizes the importation of a schedule I controlled substance ''necessary to provide for the medical, scientific, or other legitimate needs of the United States . . . in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses.'' *Id.* at 22 n.29.

While acknowledging that Lannett sought to use the substances to do various tests which are necessary to file an Abbreviated New Drug Application (ANDA) with the FDA, the ALJ relied on a DEA Policy Statement, which states that dosage form development activities do not constitute research for purposes of the CSA's registration provisions,[8] to conclude that Lannett's activities do not appear to constitute ''research'' for the purpose of section 952(a)(2)(C). *Id.* at 24. In the ALJ's view, this conclusion was significant because ''[i]f this import were under the authority of § 952(a)(2)(C), neither Rhodes nor Mallinckrodt would be entitled to a hearing to determine the details of the importation of the substances at issue or to examine any risks of possible diversion.'' *Id.* Noting that there was ''ambiguity'' as to ''the amounts that Lannett plans to import,'' and that this ''raises an issue of whether the import would preserve the closed system of distribution, or promote security, recordkeeping, and reporting requirements,'' the ALJ reasoned that the proposed importation could only be permitted ''under the authority of section 952(a)(2)(B) and therefore, [the objectors] are entitled to an on-the-record hearing'' pursuant to 21 CFR 1301.34(a).''[9] *Id.* at 25–26. The ALJ thus denied Lannett's and the Government's motions to terminate; she also denied the Government's request to take an interlocutory appeal. *Id.* at 26.

Thereafter, the ALJ conducted a hearing at which Lannett and Rhodes elicited the testimony of witnesses and introduced extensive exhibits into the record, and at which the Government also participated. Thereafter, the parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.[10] Moreover, in its post-hearing brief, the Government again maintained that Rhodes was not entitled to an adjudicatory hearing under either 21 U.S.C. § 958(i) or 21 CFR 1301.34(a), but that it was ''entitled to an informal hearing under section 952(a)(2)(C) and 958(i).'' Gov. Post-Hearing Br. at 4.

On April 6, 2010, the ALJ issued her decision. Therein, the ALJ reiterated the conclusions of her May 2008 ruling that Rhodes was entitled to an on-the-record hearing. Moreover, noting that Lannett (and the Government) also maintained that the application should be considered under section 952(a)(2)(C), the ALJ turned to the question of whether Rhodes was entitled ''to a hearing if § 952(a)(2)(B) does not apply.'' ALJ at 49. The ALJ noted that in several instances, I directed the Office of Administrative Law Judges to dismiss requests for a hearing on the application of an entity to import a narcotic raw material on the ground that the entity which had requested the hearing was not registered as a bulk manufacturer of the same substance. *See id.* (citing 72 FR 3417). The ALJ further noted that subsequent to the publication of these two **Federal Register** notices, the Agency has published (as it did in this case) notices of application for import registrations which have continued to offer hearing rights ''on proposed importations of non-narcotic raw material Schedule I or II controlled substances.'' *Id.* at 51. Reasoning that an Agency has discretionary authority to grant

[5] In its motion, Lannett also represented that it sought to import only ''approximately 3,000 capsules for the purpose of testing them in its laboratory,'' and that it was not seeking to ''import those bulk substances.'' Motion of Lannett to Dismiss and Terminate, at 6–7. However, at the hearing, Lannett's Chief Executive Officer testified that the Company was seeking permission to import (in finished dosage form) three batches of 100,000 units each. Tr. 37.

[6] Indeed, no one in the United States does. *See* Authorized Sources of Narcotic Raw Materials, 73 FR 6843, 6844 (2008) (''The United States, based on long-standing policy, does not cultivate or produce [Narcotic Raw Materials], but relies solely on opium, poppy straw, and [concentrate of poppy straw] produced in other countries for the NRM necessary to meet the legitimate medical needs of the United States.'').

[7] *Importer of Controlled Substances: Correction to Notice of Application,* 72 FR 3417 (2007) (Cody); *Importer of Controlled Substances: Correction to Notice of Application,* 72 FR 3417 (2007) (Rhodes).

[8] *See Clarification of Coincident Activities for Researchers,* 60 FR 55310 (Oct. 31, 1995).

[9] The ALJ never asked Lannett to clarify whether it was seeking permission under subparagraph B, subparagraph C, or both provisions.

[10] In light of the lengthy titles of these briefs, they will be referred to as the respective party's ''Post-Hearing Brief.'' The parties' exceptions to the ALJ's recommended decision will be referred to as their ''Exceptions.''

an on-the-record hearing to the objectors, the ALJ explained that ''there is no purpose to publishing the notice of application and affording the opportunity to object, comment, or request a hearing, unless the [Agency] intends that other importers avail themselves of the opportunity.'' *Id.* The ALJ thus concluded that the Agency ''exercised this authority, and that holding the hearing in this matter was appropriate.'' *Id.* Turning to the merits, the ALJ held that Lannett had not established that its proposed importation was permissible under section 952(a)(2)(B) because it had not shown that ''competition in the domestic market for dronabinol is inadequate and will not be rendered adequate by the registration of additional manufacturers.'' *Id.* at 53. The ALJ further rejected Lannett's contention that it was entitled to import under section 952(a)(2)(C), explaining that the purpose of section 952(a)(2) is to ''establish a strong system of domestic controls, support the domestic manufacturers who bear the cost of these controls, and [to] discourage the expansion of foreign production under less stringent controls.'' *Id.* at 53. The ALJ then observed that the legislative history of the research exception shows that it ''was intended to allow importation of substances for comparative studies on compounds developed abroad.'' *Id.* Noting that ''Lannett seeks to import a total of some 300,000 capsules,'' the ALJ reasoned that ''[w]hatever the limit may be on the quantity that qualifies for the research exception, 300,000 dosage units would likely exceed it.'' *Id.* at 54. The ALJ thus concluded that the proposed importation was not permissible under section 952(a)(2)(C) and recommended that I decline to issue a rule permitting the importation. *Id.* at 58.[11]

While the ALJ recognized that a finding that the proposed importation is permissible under either exception (2)(B) or (2)(C) is a prerequisite to obtaining a registration as an importer, ALJ at 54, she also made findings under each of the public interest factors. With respect to factor one, which directs the Agency to consider the maintenance of effective controls against diversion ''by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply . . . under adequately competitive conditions for legitimate medical, scientific, research and industrial purposes,'' the ALJ found that ''[t]here is no evidence that competition among [the] manufacturers'' of dronabinol ''or their products is inadequate.'' *Id.* at 56. The ALJ further found ''that there are currently enough registered bulk manufacturers of THC to produce an adequate and uninterrupted supply of this substance under adequately competitive conditions.'' *Id.*

With respect to factor two—the applicant's compliance with applicable State and local law—the ALJ found ''that there is not sufficient evidence in the record to make a finding.'' *Id.* As to factor three—whether the applicant's registration would promote technical advances in the art of manufacturing dronabinol or developing new substances—the ALJ found that there was no evidence on the issue. *Id.* at 57.

With respect to factor four—the applicant's conviction record of offenses related to the manufacture or distribution of controlled substances—the ALJ found that Lannett has never been convicted of such an offense and that this factor supported a finding that its registration ''would be consistent with the public interest.'' *Id.* at 57. Likewise, as to factor five—the applicant's experience in manufacturing controlled substances and the existence of effective controls against diversion—the ALJ found that Lannett ''has expertise in manufacturing and developing pharmaceutical products.'' *Id.* The ALJ also found that its security measures are adequate and ''that there is minimal risk of diversion of dronabinol at Lannett's facility.'' *Id.* The ALJ thus found that this factor supports a finding that its registration ''would be in the public interest.'' *Id.*

Finally, with respect to the sixth factor—''other factors as may be relevant to and consistent with the public health and safety''—the ALJ noted the testimony of Lannett's CEO that granting the application, ''would make more low cost generic drugs available to the public.'' *Id.* However, because Lannett did not produce ''any evidence that its proposed importation would reduce the price [of Dronabinol] to consumers,'' the ALJ concluded that ''the record does not support a finding that this factor weighs either in favor of or against'' the application. *Id.*

Summarizing her findings, the ALJ concluded that ''factor one weighs strongly against a finding that Lannett's registration would be in the public interest,'' and that while factors four and five supported granting the application, they ''are not dispositive.'' *Id.* ''[C]onclud[ing] that a preponderance of the record does not support a finding that Lannett's registration would be in the public interest,'' *id.,* the ALJ recommended that I direct the Office of Diversion Control to issue an Order to Show Cause proposing the denial of its application. *Id.* at 58.

Thereafter, both Lannett and the Government filed exceptions to the ALJ's Decision. The ALJ then forwarded the record to me for final agency action.

Having considered the record as a whole, I agree with the ALJ's holding that Rhodes was entitled to a hearing under section 958(i) even though Lannett is not a bulk manufacturer of THC. While I disagree with the ALJ's conclusion that Lannett has not established that the proposed importation is permissible under section 952(a)(2)(C), I conclude that Lannett has established that it is necessary to import only a portion of the dronabinol.

With respect to the public interest factors, while I generally agree with the ALJ's findings with respect to each of the factors, for reasons explained below, I reject her conclusion that ''factor one weighs strongly against a finding that Lannett's registration would be in the public interest.'' I further conclude that Lannett is entitled to a registration provided that it can adequately justify the amount it seeks to import; however, such registration shall be limited to authorizing it to import a quantity sufficient to conduct the studies necessary for filing an Abbreviated New Drug Application and barring it from subsequent commercial distribution of those quantities imported under this authority.

The Threshold Issue—Was Rhodes entitled to a hearing on either lannett's application for registration or its application for a rule authorizing the importation?

It is undisputed that Lannett does not hold a manufacturer's registration for THC and has never engaged in the bulk manufacture of this substance. Tr. 74. Moreover, it is undisputed that the dronabinol which Lannett seeks permission to import will be in finished dosage form. *Id.* at 37. The record also suggests that the dronabinol will have been bottled prior to the importation, that it will not be repackaged or relabeled, and that none of it will be sold commercially. Tr. 37, 164.

In their exceptions, both Lannett and the Government contend that Rhodes was not entitled to an on-the-record hearing to challenge Lannett's application. Lannett contends that because it is not a bulk manufacturer of THC, ''[t]here is no basis for a hearing under [section] 958(i)'' because this provision '' 'gives the right to request a hearing . . . only in those [cases] in which the applicant for the import registration is a bulk manufacturer and only where the person seeking the hearing is a bulk manufacturer.' '' Lannett Exc., at 2 (quoting 72 FR at 3419). Lanett further contends that the ALJ erred in construing 21 CFR 1301.34(a) to provide a hearing as doing so ''conflicts with the limitation in 21 U.S.C. § 958(i) of such hearings to cases where both the applicant and the party seeking a hearing are bulk manufacturers.'' *Id.* In Lannett's view, ''[e]ven if one considers 21 U.S.C. § 958(i) ambiguous on this issue, the ALJ's interpretation is impermissible and unsupported because it would grant to [the Agency] latitude to act in the absence of statutory prohibition rather than requiring statutory authority in the first instance.'' *Id.* (citing *Chevron U.S.A., Inc.,* v. *Natural Res. Def. Council,* 467 U.S. 837, 842–43 (1984)).

Lannett thus contends that because the regulation ''enacts 21 U.S.C. §§ 952 and 958[,] [it] cannot be read to permit what the statutes prohibit'' and that the Agency's grant of a right to a hearing to third party bulk manufacturers is an *ultra vires* act. *Id.* It likewise argues that the Agency has no discretion to grant a hearing on its application because ''there is no basis for the hearing in the statute and regulations.'' *Id.* at 3.

In its Exceptions, the Government states its agreement with the ALJ's holding that section 958(i) does not require an on-the-record hearing on either the issue of whether Lannett is entitled to be registered or whether it is entitled to a rule authorizing the importation. Gov. Exc. at 3. The Government also states that it agrees with the ALJ's holding that section 958(i) provides an

[11] *Cf. Johnson Matthey,* 67 FR 3904, 39042 (2002) (holding that applicant ''cannot be registered as an importer of NRMs unless the Deputy Administrator finds that Johnson Matthey will be allowed to import NRMs pursuant to 21 U.S.C. 952(a)(1)'').

objector with the right to a hearing on an application for an import registration, only when both the applicant and the objector are bulk manufacturers of the substances. *Id.* at 4.

The Government, however, disagrees with the ALJ's construction of section 958(i) as requiring a hearing on an application for a rule under section 952(a)(2) even where the applicant is not registered as a bulk manufacturer. *Id.* According to the Government, ''section 958(i) calls for 'a [one] hearing,' '' and ''[t]he ALJ's construction mandates a hearing under two separate circumstance, i.e.[,] when all parties are bulk manufacture[r]s and when just the objectors are bulk manufacturers.'' *Id.* The Government further reasons that because section 958(i) ''uses the conjunction 'and,' [this] indicates that both conditions, i.e.[,] the applicant being a bulk manufacturer for purpose of obtaining a registration under Section 958(a) and the objectors being bulk manufacturers for purposes of challenging the proposed importation under [section] 952(a), must be met.'' *Id.*

However, the Government then acknowledges that its argument ''may only highlight the ambiguity in the statute'' and that ''the ALJ's interpretation might be acceptable.'' *Id.* The Government further concedes that because ''it is important for DEA to scrutinize import applications under 21 U.S.C. §§ 958(a) and 823(a), the ALJ's interpretation may be preferable in terms of policy implications.'' *Id.* at 5.

The Government also takes issue with the ALJ's interpretation that 21 CFR 1301.34(a) does not require that an applicant be a bulk manufacturer to trigger the right of bulk manufacturers to a hearing on both the application for registration and the rule authorizing the import. *Id.* at 9. The Government contends that ''[w]hat the ALJ describes as 'discretion' to allow Rhodes to have a hearing under Rule 1301.34(a) (which would not otherwise be authorized under Section 958(i)) is really an interpretation of the rule to expand the persons who may obtain a hearing under Section 958(i),'' and that the Agency ''need not and should not interpret [the rule] to expand the persons who have authority to seek hearings under'' the statute. *Id.* The Government thus concludes that ''Section 958(i) and Rule 1301.34(a) do not give DEA [authority] to authorize hearings to objectors that are not authorized by law.'' *Id.*

Analysis

The resolution of this issue must, of course, begin with the language of the statute and the Agency's regulation. *Gonzales* v. *Oregon,* 546 U.S. 243, 258 (2006). Section 958(i) provides that:

Except in emergency situations as described in section 952(a)(2)(A) of this title, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, *and prior* to issuing a regulation under section 952(a) of this title authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

21 U.S.C. § 958(i).

Shortly after the CSIEA's enactment, DEA promulgated the regulation which implements this provision and which is now codified at 21 CFR 1301.34(a). *See* Proposed Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 FR 4928, 4959 (Mar. 13, 1971).[12] In its current form, the rule (which has remained unchanged throughout this proceeding), provides in relevant part:

In the case of an application for registration or reregistration to import a controlled substance listed in Schedule I or II, under the authority of . . . . 21 U.S.C. 952(a)(2)(B), the Administrator shall, upon the filing of such application, publish in the **Federal Register** a notice naming the applicant and stating that such applicant has applied to be registered as an importer of a Schedule I or II controlled substance, which substance shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that controlled substance and to any other applicant therefor. Any such person may, within 30 days from the date of publication of the notice in the **Federal Register**, file written comments on or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on the application . . . . If a hearing is requested, the Administrator shall hold a hearing on the application in accordance with § 1301.41.[13]

21 CFR 1301.34(a).

Also relevant to understanding the scope of section 958(i) and 21 CFR 1301.34(a), are the registration provisions of the Controlled Substances Act (CSA). *See* 21 U.S.C. § 823. Under the CSA, there are only two categories of registration under which a person may lawfully engage in the commercial distribution of schedule I or II controlled substances: 1) as a manufacturer, *see id.* § 823(a); and 2) as a distributor.[14] *Id.* § 823(b). However, neither the CSA nor DEA regulations define the term ''bulk manufacturer.'' *See generally id.* § 802; 21 CFR 1300.01. Nor has the Agency previously defined the term in an adjudication.

Congress did, however, define the terms ''manufacture'' and ''manufacturer.'' Under the CSA, the term ''manufacture'' is broad in scope and includes ''the production, preparation, propagation, compounding, or processing of a drug or other substance . . . and includes any packaging or repackaging of such substance or labeling or relabeling of its container.'' [15] *Id.* § 802(15); *see also id.* (''The term 'manufacturer' means a person who manufactures a drug or other substance.''). By contrast, ''[t]he term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance.'' *Id.* § 802(11); *see also id.* (''The term 'distributor' means a person who so delivers a controlled substance . . . .''). Under an Agency regulation, a manufacturer can lawfully distribute a controlled substance which it is registered to manufacture. *See* 21 CFR 1301.13(e)(1) (table of authorized coincident activities). A distributor cannot, however, lawfully manufacture (even if the activity involves packaging, repackaging, labeling or relabeling) a controlled substance. *See id.*

In section 958(i), Congress clearly instructed the Agency to provide ''an opportunity for a hearing'' on two separate issues: 1) whether to grant an application for an import registration, and 2) whether ''to issu[e] a regulation under section 952(a) . . . authorizing the importation of such a substance.'' 21 U.S.C. § 958(i). Moreover, in enacting the provision, which was enacted at the same time as the CSA, Congress was well aware that under the CSA, both manufacturers registered under section 823(a) and distributors registered under section 823(b) would have authority to engage in the commercial distribution of schedule I or II controlled substances and thus could presumably seek a registration to import a schedule I or II controlled substance.[16] *See* 21 U.S.C. §§ 823(a), 823(b).

In section 958(i), however, Congress made it clear enough that a current bulk manufacturer of a schedule I or II controlled substance is entitled to a hearing on another entity's application for registration to import a schedule I or II controlled substance, only if the applicant is itself ''a bulk manufacturer of the substance.'' 21 U.S.C. § 958(i) (''prior to issuing a registration under this section to

[12] This provision was originally codified at 21 CFR 311.42. In promulgating the final rule, the Bureau of Narcotics and Dangerous Drugs (DEA's predecessor) noted that ''[s]everal manufacturers objected strongly to the proposed § 311.42(b), (c).'' Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 FR 7776, 7777 (Apr. 24, 1971). These provisions of the proposed rule, however, involved the substantive standards for determining whether competition is adequate among domestic manufacturers ''within the meaning'' of section 952(a)(2)(B). *See id.* By contrast, the notice promulgating the Final Rule made no mention of any objections to the language of the hearing provision of subsection(a). *See id.*

[13] This regulation provides that ''[i]n any case where the Administrator shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and . . . by §§ 1301.42–1301.46 of this part, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41–1316.67 of this chapter.'' 21 CFR 1301.41.

[14] The CSA also authorizes practitioners (including pharmacies) to dispense controlled substances in schedule II (as well as practitioners conducting research with a schedule I controlled substance pursuant to an approved protocol). *See* 21 U.S.C. § 823(f). However, ''[t]he term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance.'' 21 U.S.C. § 802(11). DEA's regulations do, however, allow a practitioner (such as a pharmacy) to engage in a limited amount of distributions to another practitioner, without being registered as a distributor, ''for the purpose of general dispensing by the practitioner to patients.'' 21 CFR 1307.11(a).

[15] The term, however, ''does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substances in the course of his professional practice.'' 21 U.S.C. § 802(15).

[16] As explained above, while a distributor's registration conveys only the authority to distribute, as long as the controlled substance is not being repackaged or relabeled, a distributor acts within the scope of its registration.

a bulk manufacturer of a controlled substance in schedule I or II . . . the Attorney General shall give manufacturers holding registrations for the bulk manufacturer of the substance an opportunity for a hearing'').

Indeed, had Congress intended to provide bulk manufacturers with the right to a hearing to challenge *any application* for an importer's registration, it could have simply used the phrase ''applicant to import'' instead of ''a bulk manufacturer'' as it did in subsection (a) of this provision. *See id.* § 958(a) (''The Attorney General shall register an applicant to import . . . a controlled substance in schedule I or II if he determines that such registration is consistent with the public interest . . . .''). This language would clearly have embraced not only the situation in which the applicant for an import registration is a ''bulk manufacturer,'' but also when the applicant is a distributor of the controlled substance. *See Barnhart* v. *Sigmon Coal Co., Inc.,* 534 U.S. 438, 452 (2002) (''[W]hen 'Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'''') (quoting *Russello* v. *United States,* 464 U.S. 16, 23 (1983) (int. quotations and other citation omitted)).

As found above, Lannett is not a bulk manufacturer of THC. Moreover, as long as Lannett does not repackage or relabel the containers that the dronabinol has been packaged in by its manufacturer, Lannett does not need to hold a manufacturer's registration. Thus, it is clear that under the statute, Rhodes was not entitled to a hearing to challenge Lannett's application for a registration because the latter was not, and need not be, registered as a bulk manufacturer of THC to lawfully distribute the dronabinol for testing.[17]

By contrast, section 958(i) does not clearly provide that a bulk manufacturer's right to challenge the issuance of a regulation under section 952(a) is—as the Government and Lannett maintain—triggered only by the application of a bulk manufacturer (of the substance) to import. The relevant text of section 958(i), which immediately follows the ''prior to issuing a registration . . . to a bulk manufacturer'' clause, states: ''and prior to issuing a regulation under section 952(a) of this title authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.'' 21 U.S.C. § 958(i). Construing this provision, the ALJ reasoned that ''[b]y its plain language, this hearing right does not appear to be limited to situations in which the importer of the controlled substance is also a bulk manufacturer.'' Memorandum to Counsel and Ruling on Request for Hearing, at 21.

The Government and Lannett disagree. As noted above, the Government maintains that the insertion of the word ''and'' between the two clauses manifests that the right to a hearing on the issuance of the regulation is also triggered only when the applicant for such a regulation is a bulk manufacturer. Contrary to the Government's contention, the clause is self-contained and seems clear enough. Absent other textual evidence of an intent to limit the hearing right to where the applicant is a bulk manufacturer, Congress's use of the word ''and'' (as opposed to ''or'') to conjoin the two clauses is too thin a reed to conclude that Congress intended for the right to a hearing to challenge the issuance of a regulation under section 952 to be triggered only where an applicant is a bulk manufacturer.

Indeed, had Congress intended to limit the right to challenge the issuance of a regulation only to the instance in which the importer was a bulk manufacturer, it could have clarified that by inserting the same limitation in this clause. Moreover, the Government's proposed construction would exclude from the hearing right any application by a distributor to import a schedule I or II controlled substance. Yet, as the Government then recognizes in its brief, ''it is important for DEA to scrutinize import applications'' to ensure that the proposed import complies with Federal law. Gov. Exc., at 5. This is so whether the importer holds a manufacturer's registration or a distributor's registration.

As for Lannett, it cites the 2007 **Federal Register** notices in which I directed the Office of Administrative Law Judges to dismiss two hearings which were docketed after bulk manufacturers sought to challenge the applications of two entities to import narcotic raw materials because the requesting parties were not registered to manufacturer these substances. Lannett Exc., at 2 (citing 72 FR at 3417–19). The applications were, however, filed under section 952(a)(1), and these notices did not address the separate issue of whether section 958(i) requires the Agency to provide a bulk manufacturer with ''an opportunity for a hearing'' to challenge whether an importation is permissible under section 952(a)(2).

Lannett also argues that ''there [was] no basis for a hearing under 21 CFR 1301.34(a),'' because section 958(i) limits the hearing right ''to cases where both the applicant and the party seeking a hearing are bulk manufacturers.' '' Lannett Exc., at 2. It further contends that ''21 CFR 1301.34(a) enacts 21 U.S.C. §§ 952 and 958 and thus cannot be read to permit what the statutes prohibit.'' *Id.* at 3. Finally, Lannett argues that the ALJ erred in holding that the Agency has discretion to provide the hearing which Rhodes requested. *Id.* According to Lannett, ''[if] there is no basis for the hearing in the statute and regulations, the [Agency's] offer of the hearing was erroneous in the first instance.'' *Id.*

I conclude that it is not necessary to decide whether the ALJ correctly held that Rhodes was entitled to a full evidentiary hearing under 21 CFR 1301.34(a) even though Lannett is not a bulk manufacturer. As held above, section 958(i) obligates the Agency to provide ''an opportunity for a hearing'' to challenge whether Lannett's proposed importation complies with section 952(a). Moreover, while 21 CFR 1301.34(a) appears to limit the Agency's obligation to publish notice of the application and to grant bulk manufacturers a hearing to those instances in which a rule authorizing the importation is sought under 952(a)(2)(B) (*i.e.,* where competition among domestic manufacturers is shown to be inadequate), Lannett ignores that under 958(i), the only instance in which the Agency is not obligated to provide a hearing is ''in emergency situations as described in section 952(a)(2)(A) of this title.'' 21 U.S.C. § 958(i); *see also id.* § 952(a)(2)(A) (authorizing importation of ''such amounts of any controlled substance in schedule I or II . . . that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs . . . during an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate''). Accordingly, the plain language of section 958(i) obligates the Agency to provide an opportunity for a hearing to a bulk manufacturer even when importation is sought ''in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses[.]'' *Id.* § 952(a)(2)(C).[18]

[17] To make clear, if an applicant for an importer's registration will engage in an activity (such as repackaging or relabeling) which requires that it obtain a manufacturer's registration, it cannot circumvent the hearing requirement of 958(i) by failing to apply for a manufacturer's registration. However, Lannett's proposed activities with the dronabinol do not require that it obtain a manufacturer's registration.

It is noted that on DEA's Application for Registration (Form 225), the Agency recognizes both ''Manufacturer'' and ''Manufacturer BULK'' as different categories of ''Business Activity.'' The Application further recognizes four different stages of manufacturing: 1) ''Bulk synthesis/extraction,'' 2) ''Dosage Form manufacture,'' 3) ''Package/Repackage'' and ''Label/Relabel,'' and 4) ''Non-human consumption.'' However, the Agency has not defined by regulation the term ''Bulk Manufacturer'' and the Government has provided no guidance in this case as to the Agency's view on what distinguishes a ''Bulk Manufacturer'' from a ''Manufacturer'' and which of the above stages it considers to be bulk manufacturing. In any event, because Lannett need not engage in any of the four stages to conduct its tests, it is clear that it does not need to be registered as either a bulk manufacturer or manufacturer.

[18] Subparagraph (2)(C) was not part of the Act as originally enacted in 1970. *See* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91–513, § 1002(a)(2), 84 Stat. 1236, 1285 (1970). Section 1008(h) of the 1970 Act provided the hearing requirement which is now codified at 21 U.S.C. § 958(i). *See* 84 Stat. 1289 (''prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing'').

In 1984, Congress amended the statute to add subparagraph (2)(C). *See* Continuing Appropriations, 1985-Comprehensive Crime Control Act of 1984, Pub. L. 98–473, § 520, 98 Stat. 1837, 2075 (1984) (codified at 21 U.S.C. § 952(a)(2)(C)). While in this statute, Congress redesignated subsection (h) as subsection (i), it did not amend the hearing requirement to limit it to those cases in which importation was sought on the ground that competition is inadequate. *See id.* § 525, 98 Stat. 2076–77.

As for Lannett's argument that the regulation is *ultra vires* because it provides for a hearing on the issue of its registration when the statute does not, it is noted that the ALJ's pre-hearing ruling was somewhat unclear as to whether Rhodes was

Continued

In her various rulings, the ALJ concluded that section 958 does not require that the Agency provide an ''on the record'' hearing as part of the rulemaking process under section 952(a). ALJ Memorandum to Counsel, at 21; ALJ at 48. This holding is amply supported by Supreme Court precedent. *See United States* v. *Florida East Coast Ry.,* 410 U.S. 224 (1973); *see also United States* v. *Allegheny-Ludlum Steel Corp.,* 406 U.S. 742 (1972).

To the extent Lannett contends that the Agency did not have discretion to grant Rhodes a formal hearing on its application (in essence, an argument that the Agency has granted too much process), the Supreme Court has long recognized that ''the formulation of procedures was basically left within the discretion of the agencies to which Congress had confided the responsibility for substantive judgments.'' *Vermont Yankee Nuclear Power Corp.,* v. *NRDC, Inc.,* 435 U.S. 519, 524 (1978). As the Court recognized, ''this principle [is] 'an outgrowth of the congressional determination that administrative agencies and administrators will be familiar with the industries which they regulate and will be in a better position than federal courts or Congress itself to design procedural rules adapted to the peculiarities of the industry and the tasks of the agency involved.'' *Id.* at 525 (quoting *FCC* v. *Schreiber,* 381 U.S. 279, 290 (1965)). *See also FCC* v. *Pottsville Broadcasting Co.,* 309 U.S. 134, 143 (1940) (administrative agencies ''should be free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties''). Consistent with this authority, this Agency has long held that the Administrator has discretion under section 958(i) to grant or deny a hearing to any party on issues concerning the importation of controlled substances even where the party seeking the hearing was not entitled to a hearing because it did not hold a registration to manufacture the substance sought to be imported. *See Importation of Controlled Substances—Application,* 43 FR 35403 (1978) (McNeilab, Inc.).[19] Because it is clear that under section 958(i), Rhodes was entitled to a hearing on the issue of whether a regulation should issue authorizing the importation, I conclude that it is within the Agency's discretion to provide a formal hearing on the application.

Is Lannett's proposed importation permissible under Section 952(a)(2)?

Under section 952(a)(2), it is unlawful to import into the United States a schedule I or II controlled substance ''except that . . . such amounts of any controlled substance in schedule I or II . . . that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States'' may be imported if one of three findings is made. 21 U.S.C. § 952(a)(2). These are:

(A) During an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate,

(B) [i]n any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 823 of this title, or

(C) in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses[.]

21 U.S.C. § 952(a)(2).

In its Post-Hearing Brief, Lannett contends that its proposed importation is permissible under both subparagraphs B and C.[20] Lannett's Post-Hearing Br., at 6–7. While the Government took no position on whether the importation is permissible under subparagraph B, it argues that ''Lannett's application should be assessed under'' subparagraph C and appears to endorse Lannett's position that the importation is permissible on this basis. Gov. Post-Hearing Br., at 11; *see also id.* at 12 (''The phrase 'limited quantities exclusively for . . . research uses' should not be construed to have a numerical limit. If the amounts are definitive and will be used for research, then Section 952(a)(2)(C) should apply.''). By contrast, Rhodes argues that Lannett has not established that the proposed importation is permissible under either provision. Rhode's Post-Hearing Br., at 66–77.

In its Exceptions, Lannett further argues that because its application presents ''no increased risk of diversion,'' the Agency can grant its application ''without regard to 21 U.S.C. § 952(a).'' Lannett's Exc., at 3. In Lannett's view, because the overarching purpose of the CSA and the CSIEA is to prevent the diversion of controlled substances, and there is no evidence that granting its application will increase the risk of diversion, DEA can disregard section 952(a). *Id.* at 3–4. As support for this proposition, Lannett cites *Penick Corp.* v. *DEA,* 491 F.3d 483, 489 n.8 (D.C. Cir. 2007), and *Noramco of Delaware, Inc.,* v. *DEA,* 375 F.3d 1148, 1153 (D.C. Cir. 2004), both of which upheld Agency decisions to grant registrations to importers of narcotic raw materials under 21 U.S.C. § 958(a) without analyzing the adequacy of competition under factor one of the public interest standard (21 U.S.C. § 823(a)(1)) because there was no evidence that granting the registration would increase the risk of diversion.

Lannett's argument fails, however, because both cases involved an application of the Agency's discretionary authority under the public interest standard used to determine whether to grant an application for registration, and not whether an importation was permissible under section 952(a)(2)(B). *See Penick,* 491 F.3d at 486–488 n.5;[21] *Noramco,* 375 F.3d at 1153. As the D.C. Circuit recognized in *Penick,* ''section 823(a)'s enumerated factors represent components of the public interest rather than independent requirements for registration and thus, the [Agency] may find a registration consistent with the public interest even if one (or possibly more) of the public interest factors is not satisfied.'' 491 F.3d at 490 (citing *Johnson Matthey, Inc.,* 60 FR 26050, 26052 (1995) (''It is well established that the Deputy Administrator is not required to make findings with respect to each of the [section 823(a)] factors, but has discretion to give each factor the weight he deems appropriate, depending upon the facts and circumstances in each case.'')); *cf. Air Line Pilots Ass'n* v. *Dep't of Transp.,* 791 F.2d 172, 177–78 (D.C. Cir. 1986).

By contrast, section 952(a)(2) sets forth the affirmative requirement that the Agency make one of three findings before issuing a regulation approving a proposed importation of a schedule I or II controlled substance. As section 952 makes plain, DEA does not have discretion under the statute to authorize an importation in the absence of a finding that one of the three conditions exists. Accordingly, I reject Lannett's argument that because there is no evidence that the importation will increase the risk of diversion, the Agency can grant its application without regard to whether its proposed importation is permissible under section 952.

A. Is Lannett's proposed importation permissible under Subparagraph B?

As the ALJ recognized, to import pursuant to this provision, an applicant must show that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers. ALJ at 52. In her decision, the ALJ found that Lannett had failed to establish that competition among domestic manufactures of dronabinol is inadequate. ALJ at 52–53. More specifically, she noted that Lannett's evidence was largely confined to the testimony of its CEO as to several

entitled to a hearing on the issue. *See* Memorandum to Counsel and Ruling on Request for Hearing, at 26 (''I have found that the only exception to the general prohibition of importation of controlled substances that would apply here is an importation authorized under § 952(a)(2)(B). Therefore, I find that Rhodes [is] entitled to a formal 'on the record' hearing on the application[ ] to import the substance that [it] respectively holds registration to bulk manufacture.''). However, Lannett did not seek clarification from the ALJ as to whether the hearing would encompass the public interest factors applicable to the issue of its registration, and it chose to put on evidence on the factors. I thus conclude that it has waived its argument.

[19] I acknowledge that the 2007 Notice of Correction called into question the Agency's discretionary authority to hold hearings in cases involving narcotic raw materials where the parties who requested a hearing were not manufacturers of the substance as required under both section 958(i) and 21 CFR 1301.34(a). However, as explained above, under section 958(i), Rhodes was entitled to a hearing to challenge the issuance of a regulation authorizing the importation.

[20] Lannett does not claim that an emergency exists because domestic supplies of dronabinol are inadequate.

[21] Indeed, in *Penick,* the D.C. Circuit noted that the objectors did not challenge the rulemaking aspect of the proceeding. *See* 491 F.3d, at 488 n.5. Moreover, under section 952(a)(1), the importation of narcotic raw material does not require a finding of inadequate competition. *See* 21 U.S.C. § 952(a)(1) (authorizing importation of ''such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves . . . as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes'').

unsuccessful efforts the company made to find a domestic manufacturer/supplier of dronabinol during the period of 2002–2003. ALJ at 53. The ALJ further noted that ''Lannett did not offer any evidence as to the market for bulk dronabinol in 2009,[22] about competition in that market, or about the factors'' set forth in the Agency's regulation for determining whether competition among the domestic manufacturers of bulk dronabinol is inadequate. *Id.* (citing 21 CFR 1301.34(d), (e), and (f)).[23]

As for Lannett's evidence regarding its inability (circa 2002–03) to find a domestic manufacturer to supply it, the ALJ properly held that this evidence was too stale to support a finding of inadequate competition. Notably, the statutory text requires a finding that competition ''*is inadequate and will not be rendered adequate* by the registration of additional manufacturers.'' 21 U.S.C. § 952(a)(2)(B) (emphasis added). Consistent with the statute, DEA has previously held that the relevant time period for assessing the adequacy of competition is at the time of the hearing. *Cf. Penick Corp., Inc.,* 68 FR 6947, 6950 (2003) (''The Deputy Administrator agrees with the ALJ that Penick has demonstrated that the opiate API market was not operating under 'adequately competitive conditions' as of the date of the hearing.''). Moreover, Lannett offered no evidence to rebut Rhode's contention that there are currently multiple domestic manufacturers which are able to supply the bulk dronabinol market. Tr. 387–88; RX 28, at 5–7. Accordingly, I agree with the ALJ that Lannett has failed to show that proposed importation is permissible under section 952(a)(2)(B).

A. Is Lannett's proposed importation permissible under Subparagraph C?

Lannett (supported by the Government) argues that the importation is nonetheless permissible under the exception for '' 'limited quantities exclusively for scientific, analytical, or research uses.' '' Lannett's Exc., at 7 (quoting 21 U.S.C. § 952(a)(2)(C)). As found above, the evidence shows that Lannett seeks to import three batches of 100,000 dosage units each for the purpose of conducting testing to establish the stability of the drug and to show that the dronabinol is bioequivalent to Marinol, the FDA-approved legend drug; Lannett will then submit the data to the FDA as part of an ANDA. Lannett also established that the reason why the test batches are 100,000 dosage units is because the FDA generally requires that the test batch be the same size as the eventual production batch and that if Lannett's ANDA is approved, it does not want to limit the production batches ''to less than 100,000 dosage units per batch.'' LX 1, at 3–4; LX 4, at 6 (''OGD's Procedure and Policy Guide . . . 22–90 . . . requires that the test batch size be determined based on the proposed production batch.''); *see also* 21 CFR 314.94(a)(9) (an ANDA ''shall contain the proposed or actual master production record . . . to be used for the manufacture of a commercial lot of the drug product'').

Lannett's CEO also testified that as a general matter, to comply with FDA's standards, three batches must be produced to validate the manufacturing process, although the batches need not necessarily be made consecutively. Tr. 37–39. However, the FDA's *Guidance on the Packaging of Test Batches* states that ''ANDAs . . . are usually approved based on data from a single test batch.'' LX 3, at 1. Moreover, it is not clear why the validation of the additional batches requires that they be imported into the United States.[24]

The ALJ concluded that the proposed importation is not permissible under subparagraph C. In so concluding, the ALJ relied on the testimony of a former agency official who was involved in drafting the provision and reasoned that the legislative history of the amendment indicates ''that (1) the purpose of the broad prohibition on importing Schedule I and II bulk active pharmaceutical ingredients was to establish a strong system of domestic controls, support the domestic manufacturer who bears the cost of these controls, and discourage the expansion of foreign production under less stringent controls; and (2) the research exception from the prohibition was intended to allow importation of substances for comparative studies on compounds developed abroad.'' ALJ at 53.

The ALJ also relied on a 1995 Policy Statement which was issued in response to the practice of some companies that were engaging in dosage-form development activities, including bulk manufacturing, without obtaining a manufacturer's registration; these firms claimed that their activities were coincident activities which could be lawfully performed under a researcher's registration. *Id.* at 54; *see also Clarification of Coincident Activities for Researchers,* 60 FR 55310, 55311 (1995).[25]

The ALJ observed that ''[a] major concern expressed in the *Clarification* was that some dosage form manufacturers had obtained large quantities of Schedule II substances under a researcher registration and did not have in place the safeguards required of a firm registered to manufacture. A continuing theme in discussions of the research exception is that the quantities involved are small.'' ALJ at 53–54. Noting that Lannett seeks to import 300,000 capsules, the ALJ reasoned that ''[w]hatever the limit may be on the quantity that qualifies for the research exception, 300,000 dosage units would likely exceed it.'' *Id.* The ALJ thus found that the importation ''does not qualify as an importation for research purposes within the meaning of 21 U.S.C. § 952(a)(2)(C).''

As originally enacted, subsection 952(a)(2) did not contain this provision. *See* 84 Stat. 1242. Rather, the exception was enacted as part of the Dangerous Drug Diversion Control Act of 1984. *See* Continuing Appropriations, 1985-Comprehensive Crime Control Act of 1984, Public Law 98–473, tit. V, § 520, 98

[22] It is acknowledged that Lannett introduce several exhibits providing data as to the price of dosage-form dronabinol over a multi-year period which concluded shortly before the hearing convened. This data included the average unit and wholesale prices of dronabinol (both generic and branded) sold by various manufacturers and distributors to non-retail settings, as well as the average retail price of a prescription for various strengths and quantities of both the generic and branded drugs (which were also listed by manufacturer) at retail and mail-order pharmacies. LX 5–8. Lannett did not, however, offer any evidence as to the costs of bulk dronabinol in the domestic market at the time of its application.

While the average wholesale and retail prices of dosage form dronabinol might provide some evidence that competition is inadequate among the domestic manufacturers of bulk dronabinol, Lannett did not put on any testimony, let alone that of an expert, to explain how this evidence shows that competition in the bulk dronabinol market is inadequate. Moreover, Lannett does not even cite this evidence in its brief.

[23] Summarized, these factors include: 1) ''[t]he extent of price rigidity''; 2) ''[t]he extent of service and quality competition among the domestic manufacturers for shares of the domestic market''; 3) ''[t]he existence of substantial differentials between domestic prices and the higher of prices generally prevailing in foreign markets or the price at which the applicant . . . is committed to undertake to provide such products in the domestic market in conformity with the Act''; 4) ''[t]he existence of competitive restraints imposed upon domestic manufacturers by governmental regulations''; and 5) ''[s]uch other factors as may be relevant to the determinations required under this paragraph.'' 21 CFR 1301.34(d).

DEA regulations further direct that ''[i]n considering the scope of the domestic market, consideration shall be given to substitute products which are reasonably interchangeable in terms of price, quality and use,'' *id.* § 1301.34(e); and ''[t]he fact that the number of existing manufacturers is small shall not demonstrate, in and of itself, that adequate competition among them does not exist.'' *Id.* § 1301.34(f).

[24] According to FDA's recently published *Guidance for Industry, Process Validation: General Principles and Practices* (Jan. 2011), of which I take official notice, FDA Current Good Manufacturing Process ''regulations define the various aspects of validation. For example, § 211.110(a), *Sampling and testing of in-process materials and drug products,* requires that control procedures '' '. . . be established to monitor the output and *to validate* the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.'' ' '' *Process Validation,* at 6. Continuing, the Guidance states that ''[u]nder this regulation, even well-designed processes must include *in-process* control procedures to assure final product quality.'' *Id.* (emphasis added).

[25] The *Clarification* specifically noted that some of these firms were engaged in the ''production of batches as mandated by the'' FDA and further stated that:

[f]or purposes of 21 CFR part 1301, the following dosage form development activities are not considered research and must be conducted under a manufacturer registration: (a) Activities for the purpose of satisfying regulatory requirements such as FDA submission or good manufacturing practice; (b) activities associated with establishing the manufacturing processes and procedures, including, but not limited to, production of material used for pilot, scale-up and reformulation studies, as well as the studies themselves; and (c) all activities associated with such development including, but not limited to, bioavailability, formulation, stability, and validation. While these activities may be considered research under FDA requirements, 21 CFR part 1301 must be read within the context of the CSA and its attendant requirements concerning quotas, recordkeeping, security and reporting. DEA does not consider such dosage form development to be a coincident research activity as contemplated by 21 CFR 1301.22(b); the production of material for such activities is manufacturing.

60 FR at 55311.

Stat. 1837, 2075 (1984). Significantly, neither the statute nor the Agency's regulations define the provision's critical terms of ''in limited quantities'' and ''exclusively for scientific, analytical, or research uses.'' 21 U.S.C. § 952(a)(2)(C). *See id.* § 951 (defining only the terms ''import'' and ''customs territory of the United States'' and otherwise providing that the definitions of the CSA apply); *id.* § 802 (CSA's definitions); *see also* 21 CFR Part 1300; *id.* § 1312.02.

Rhodes points to the legislative history of both the original CSIEA and the Amendment, as well as the testimony of the former DEA official who was involved in drafting the provision, and contends that subparagraph (2)(C) was only intended to address the statute's failure to provide a mechanism (as had a Treasury Department regulation enacted under the Narcotic Manufacturing Act of 1960) to allow researchers to import foreign-source materials to perform comparative studies on them when the domestic supply is inadequate because the foreign-source material is unique and/or to develop reference standards. Rhodes Post-Hearing Br. at 76; RX 31, at 20–23. Rhodes cites the written testimony of the former official, who, in turn, cites the Senate Report Committee Report, which states:

Under current 21 U.S.C. 952(a)(2), the importation of controlled substance in Schedules I and II . . . for medical, scientific, and other legitimate purposes is generally limited to those cases in which there is a finding that competition among domestic manufactures is inadequate. This requirement has created difficulties in situations which routinely arise when researchers need specific substances for comparative studies on foreign-developed compounds that are unique in their manufacture. Section 518 [this amendment] would accommodate the need to import such substances by adding a new provision to 21 U.S.C. 952(a)(2) that would allow importation of limited quantities of controlled substances for purposes exclusive of ultimate scientific, analytic, or research uses.

S. Rep. No. 98–225, at 269–70, *reprinted at* 1984 U.S.C.C.A.N. 3182, 3451–52.

According to the former official:

The principal purpose of this statutory amendment was . . . to restore an important exception to the prohibition that had (perhaps inadvertently) been left out of the 1970 Act. The commercial purposes for which Lannett wishes to import these substances merely to satisfy FDA regulatory requirements, in my view, certainly do not relate to the purpose for which this amendment is intended. These are not unique substances or laboratory standards, and are not being sought for any such characteristics or purposes.

RX 31, at 21. Rhodes thus argues that because Lannett's purpose in importing the dronabinol is to establish that it is bioequivalent to the domestically-produced innovator drug and not to show that it is a unique substance, ''its proposed importation does not fit within the purposes for which th[e] provision is intended.'' Rhodes Post-Hearing Br. at 75.

Rhodes also argues that its position is supported by 21 CFR 1312.13(a)(3) & (4), which were promulgated to implement section 952(a)(2)(C). *Id.* at 75–76. As Rhodes observes, this regulation ''requires a finding 'that the domestic supply of any controlled substance is inadequate for scientific studies, and that the importation of that substance for scientific purposes is only for delivery' '' to a person registered or exempt from registration under section 957 and 958, ''or 'that the importation of the controlled substance is for ballistics [26] or other analytical or scientific purposes, and that the importation of that substance is only for delivery''' to a person registered or exempt from registration under section 957 and 958. *Id.* (quoting 21 CFR 1312.13(a)(3) & (4)). According to the former agency official, ''it is no accident that the terminology used in subsections 1312.13(a)(3) and (a)(4) reflects the language previously cited in the Treasury Department regulations implementing the Narcotics Manufacturing Act of 1960.'' RX 31, at 22.[27] Rhodes further argues that a narrow reading of the term ''research'' is supported by the longstanding Federal policy which prohibited the importation of narcotic drugs with limited exceptions for narcotic raw materials as were necessary to provide for medical and other legitimate uses. Rhodes Resp. to Gov's. & Lannett's Exceptions, at 10–11 (citing Narcotic Drugs Import and Export Act, § 2(b), Public Law 67–227, 42 Stat. 596 (1922)).

It cannot be disputed that prior to the enactment of the CSIEA, longstanding Federal policy prohibited the importation of narcotics other than raw materials such as crude opium and coca leaves. The CSIEA, however, substantially modified this policy by allowing for the importation of additional controlled substances, including not only schedule I and II drugs, in accordance with the provisions of subsection 952(a)(2), but also nonnarcotic schedule III through V drugs, under the provisions of subsection 952(b). *See* 21 U.S.C. § 952(b). Significantly, in the case of a nonnarcotic schedule III controlled substance, the latter provision does not condition approval of a proposed importation upon a finding that competition among domestic manufacturers of the drug is inadequate. Rather, the statute requires only that the drugs be ''imported for medical, scientific, or other legitimates uses,'' and that ''in the case of any nonnarcotic controlled substance in schedule III, [pursuant to] such import permit, notification, or declaration, as the Attorney General may by regulation prescribe.'' *Id. See also* 21 CFR 1312.30(a) (requiring import permit for synthetic dronabinol in sesame oil encapsulated in soft gelatin in an FDA approved product). Given that the CSIEA fundamentally changed Federal policy as to the scope of permissible importations of controlled substances, its provisions, and not historical practice, are dispositive.[28]

Thus, even conceding Rhodes' contention that ''[t]he principal purpose'' of the provision was to restore the exception provided for under the Treasury Department regulation, that does not mean that this was Congress' *exclusive purpose.* To the contrary, the statutory text is the best evidence of Congress's purpose, *see West Va. Univ. Hospitals, Inc.,* v. *Casey,* 499 U.S. 83, 98 (1991); and section 952(a)(2)(C)'s text is substantially broader in scope than what was necessary to effectuate the purpose indicated in the legislative history of limiting the exception to allowing researchers to obtain ''specific substances for comparative studies on foreign-developed compounds that are unique in their manufacture.'' S. Rep. No. 98–225, at 269–70.

Moreover, under the former Treasury Department regulation, importation ''for the purpose of research or spot check analyses to establish or maintain proper chemical and therapeutical standards of their products'' was deemed to be ''for scientific purposes.'' 21 CFR 307.151 (1962). Other than the fact that Lannett seeks to do the stability and bioequivalence studies to support an ANDA (and eventually market a drug), there is little difference between the nature of these studies and those permitted under the former regulation. Indeed, as is made clear by the testimony of the former official, it is not the

[26] The former official explained that the term ''ballistics'' ''refers to the scientific examination of drugs, typically in dosage form, by forensic chemists to determine their origin, properties, identifying marks, or impurities, usually for evidentiary purposes.'' RX 31, at 22.

[27] Under former 21 CFR 307.151, the Commissioner of Narcotics was authorized to ''issue a formal permit to certain classes of persons desiring to import any narcotic drug or drugs . . . for scientific purposes only.'' Under this regulation, importation was ''limited to narcotic drugs not readily available to the applicant from sources within the United States, unless questions of origin, types or particular methods of productions are elements of the research objectives.''

The regulation, however, further provided that:

Applicants for import permits licensed under section 8 of the Narcotics Manufacturing Act of 1960, who as part of their manufacturing business maintain branch or subsidiary manufacturing establishments in foreign countries, or are themselves a branch or subsidiary of a foreign parent organization, may be issued import permits for occasional imports of samples of the products of these foreign branches, subsidiaries or parent organizations for the purpose of research or spot check analyses to establish or maintain proper chemical and therapeutical standards of their products. However, an applicant will not be granted import permits to make continuous or regular imports of samples of recurring batches or lots of the same product for routine factory controls.

Id. Section 8 of the 1960 Act was the predecessor of 21 U.S.C. § 823(a) and required that ''every person'' engaged in the manufacture of narcotic drugs obtain ''a separate license for the manufacture of each basic class of narcotic drug.'' Narcotics Manufacturing Act of 1960, § 8, Public Law 86–429, 74 Stat. 55, 62 (1960).

[28] As noted above, the ALJ also reasoned that ''the purpose of the broad prohibition on importing Schedule I and II bulk active pharmaceutical ingredients was to establish a strong system of domestic controls, support the domestic manufacturers who bear the cost of these controls, and discourage the expansion of foreign production under less stringent controls.'' ALJ at 54. However, Lannett is not seeking to import ''bulk active pharmaceutical ingredients,'' but rather a drug in finished dosage form. Moreover, both the manufacturers of the active pharmaceutical ingredient and the finished dosage form are located in Switzerland, a country which is a party to the Single Convention on Narcotic Drugs, and which has agreed to comply with extensive control measures.

nature of the activity which Lannett will use the dronabinol for, but the fact that it seeks to eventually commercially distribute the drug which, in Rhodes' view, bars the importation under the research exception.

However, performing stability and bioequivalence studies on a drug clearly constitutes a ''scientific, analytical or research use[]'' as required by the statute even if these activities are being done for the purpose of being able to obtain approval to commercially distribute a drug. While subsection (a)(2)(C) further requires that the importation be ''exclusively'' for these purposes, effectuating the statutory mandate can be accomplished by prohibiting the subsequent commercial distribution of any of the drugs imported under this provision.

Contrary to Rhodes' position, neither the Agency's regulation nor the 1995 Policy Statement preclude the Agency from construing 952(a)(2)(C) to permit the importation. Under the regulation, the Agency may authorize an importation upon a finding that ''the controlled substance is for ballistics *or other analytical or scientific purposes.*'' 21 CFR 1312.13(a)(4) (emphasis added). Notably, the regulation does not contain any language limiting the scope of what constitutes ''analytical or scientific purposes.'' *Id.* Thus, on its face, the regulation clearly permits importation to establish stability and bioequivalence of a drug.

The ALJ's reliance on the 1995 Policy Statement was also misplaced. Most significantly, the Policy Statement did not address the issue of what activities constitute ''scientific, analytical, or research uses'' under subsection 952(a)(2)(C), but rather the question of whether manufacturers could engage in ''the production of material'' in batch sizes for dosage-form development activities under a researcher's registration. 60 FR at 55311. The scale of the latter activity clearly raised a variety of concerns involving the security and recordkeeping of the bulk active pharmaceutical ingredients used in the manufacturing process, and DEA's regulations have long imposed far more extensive security and recordkeeping requirements on manufacturers than they have on researchers. *Compare* 21 CFR 1304.22(a) (recordkeeping requirement for manufacturers) *with id.* 1304.22(c) (recordkeeping requirements for researchers); *compare* 21 CFR 1301.72 and 1301.73 (physical security controls for non-practitioners) *with id.* 1301.75 (physical security controls for practitioners and researchers).

While these concerns remain valid, they are not implicated by Lannett's proposed importation. Notably, Lannett seeks to import controlled substances which are already in finished dosage form and packaged. The importation thus does not raise the same security and recordkeeping concerns as does the practice of manufacturing large batches of dosage form drugs from active pharmaceutical ingredients. Because the 1995 Policy Statement clearly did not consider this situation, I decline to give it any weight in the analysis. *Cf. Skidmore* v. *Swift & Co.,* 323 U.S. 134, 140 (1944).

Subsection (a)(2)(C) does, however, require that the importation be ''in limited quantities.'' Based on this requirement, the ALJ reasoned that ''[w]hatever the limit may be on the quantity that qualifies for the research exception, 300,000 dosage units would likely exceed it.'' ALJ at 54.

As noted above, in enacting this provision, Congress did not define the term ''limited quantities.'' I conclude that the best reading of this provision is that it does not impose an absolute numerical limit on the size of a permissible importation, but rather, requires an assessment of the quantity sought to be imported in light of the substance's intended use.

Accordingly, while the absolute size of a proposed importation does not necessarily render it impermissible, absent a clear justification to support the quantity, the importation does not comply with the ''limited quantities'' standard. An applicant must therefore justify the amount of the proposed importation based on the underlying purpose of the research.[29] However, where the applicant justifies the amount of the proposed importation, the importation qualifies as ''in limited quantities.''

Here, Lannett's evidence shows that FDA generally requires that the test batch be the same size as the eventual production batches and that these batches should be 100,000 dosage units. LX 1, at 3–4; LX 3, at 1–2. Moreover, according to the FDA Guidance, the samples which are used to conduct stability and bioequivalency tests should be selected from ''packaged product'' and should either ''be systematically selected at intervals from the packaging line,'' or selected by ''a random sampling procedure.'' LX 3, at 3–4. The same FDA Guidance Document includes a table for solid oral dosage form drugs indicating the number of bottles that should be selected based on the number of dosage units in a package. *Id.* at 4. This table suggests that where a drug is packaged in 100 dosage unit bottles, only twenty-eight bottles are needed for the requisite stability and bioequivalence studies and for reserves; this table thus also suggests that a figure closer to Lannett's original request to import 3,000 dosage units may suffice. *Id.* Moreover, even crediting the testimony that validating the manufacturing process requires the production of three batches, Lannett has not established why it is necessary for it to import the additional two batches.

It is further noted that under an FDA regulation, that Agency ''strongly recommends that . . . any person planning to conduct a bioavailability or bioequivalence study submit the proposed protocol for the study to FDA for review prior to the initiation of the study'' and that FDA ''will offer advice with respect to whether'' the design of the ''study is appropriate'' and whether ''[t]he proposed chemical and statistical analytical methods are adequate.'' 21 CFR 320.30. Lannett should therefore submit its protocol for review by the FDA and should obtain advice from FDA as to whether its study will be acceptable if the samples are selected prior to importation at the manufacturer (as the Guidance suggests) rather than selected after importation. Lannett should then submit its protocol and the FDA's review of the protocol to this Agency. If Lannett still seeks to import the remaining two batches, it must provide further evidence to support its contention that these batches need to be imported to validate the manufacturing process.

Accordingly, I conclude that conducting stability and bioequivalency testing constitutes ''scientific, analytical, or research uses'' and is a permissible basis for importing a schedule I or II controlled substance under section 952(a)(2)(C). However, before the Agency issues a regulation approving Lannett's proposed importation, Lannett must demonstrate that the quantity is ''limited'' in accordance with the above discussion.

* * * * *

While I hold that the importation of a schedule I or II controlled substance for the purpose of conducting stability and bioequivalency testing in support of an ANDA is permissible under section 952(a)(2)(C), the provision must be construed in a manner that also gives effect to the language of 952(a)(2)(B). Accordingly, any controlled substances which are imported under the authority of 952(a)(2)(C) cannot thereafter be commercially distributed. Moreover, where an importer succeeds in obtaining FDA approval to market a drug, subsequent importation of the drug for commercial distribution must comply with the applicable provision of section 952. Thus, where an FDA-approved drug has been placed in schedule II, or involves a narcotic drug in schedules III through V, an applicant will be granted permission to import only if it establishes ''that competition among domestic manufacturers is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 823.'' 21 U.S.C. § 952(a)(2)(B).

Is Lannett entitled to a registration?

As held above, section 958(i) does not provide a bulk manufacturer with the right to a hearing on the issue of whether Lannett was entitled to a registration. While the ALJ recognized as much, she nonetheless allowed the objectors to litigate the issue and made recommended findings. *See* ALJ at 48, 55–58. The ALJ further concluded that granting Lannett's application for registration would be inconsistent with the public interest. *Id.* at 58.

Having concluded that the objectors were not entitled to a hearing on the issue of whether Lannett was entitled to be registered,

[29] DEA has extensive regulations governing the conduct of research using controlled substances. For example, under DEA's regulations, a researcher is required to submit a protocol setting forth, *inter alia,* a ''[d]escription of the research to be conducted, including the number and species of research subject, the dosage to be administered, the route and method of administration, and the duration of the project,'' as well as a ''[s]tatement of the security provisions for storing the controlled substances . . . and for dispensing [them] in order to prevent diversion.'' 21 CFR 1301.18(a). Moreover, ''[i]n the case of a clinical investigation with controlled substances listed in Schedule I, the application shall submit three copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) together with a statement of the security provisions . . . to, and have such submission approved by, the'' FDA. *Id.* 1301.18(b).

the ALJ should not have allowed the objectors to litigate the issue. However, because Lannett may be entitled to the issuance of a rule authorizing the importation, I conclude that it is appropriate to issue a declaratory order on the issue of whether Lannett has established its entitlement to be registered. *See* 5 U.S.C. § 554(e) (''The agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.'').

Pursuant to section 303(a) of the CSA, ''[t]he Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.'' 21 U.S.C. § 823(a). ''In determining the public interest,'' section 303(a) directs the Attorney General to consider the following factors:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substances in schedule I or II compounded there from into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with public health and safety.

Id. It is well settled that the Agency need not make findings as to all of the factors and that it may give each factor the weight it deems appropriate in determining the public interest. *See Novelty, Inc.,* v. *DEA,* 571 F.3d 1176, 1181 (D.C. Cir. 2009).

While there is insufficient evidence to make findings with respect to factors two, three, and six, the record establishes that Lannett has experience in the manufacture and development of pharmaceutical products and that it maintains effective controls against diversion (factor five). The record also establishes that Lannett has not been convicted of an offense related to the manufacture or distribution of controlled substances (factor four). Both of these findings support the conclusion that granting Lannett's application for a registration would be consistent with the public interest.

The ALJ found that Lannett had not shown that competition among domestic manufactures of dronabinol is inadequate and that the current manufacturers were incapable of producing an adequate and uninterrupted supply of this substance (factor one). Relying on *Lyle E. Craker,* 74 FR 2101 (2009), the ALJ thus concluded this factor ''weighs strongly against a finding that Lannett's registration would be in the public interest,'' and concluded that the record does not support granting its application.

I conclude, however, that *Craker* does not require that Lannett's application be denied. As the D.C. Circuit has held, ''section 823(a)'s enumerated factors represent components of the public interest rather than independent requirements for registration and thus, the [Agency] may find a registration consistent with the public interest even if one (or possibly more) of the public interest factors is not satisfied.'' *Penick,* 491 F.3d at 490. As *Penick* recognized, the principal purpose of factor one is to provide the Agency with authority ''to maintain control over diversion 'by limiting the [number of firms engaged in the] importation and bulk manufacture' of controlled substances.'' *Id.* at 491.

Craker involved an application to manufacture a schedule I controlled substance on a continuing basis. By contrast, the activity for which Lannett seeks an importer's registration (to perform stability and bioequivalency testing) does not involve an activity of a continuing nature, but rather, three separate acts (at most) of importation. As such, granting its application does not raise the same concerns with respect to the Agency's ability to maintain effective controls against diversion.

Accordingly, I conclude that factor one does not preclude the issuance of an import registration to Lannett, subject to the condition that its authority to import dronabinol as a schedule I drug be limited to the quantity which is necessary to support an ANDA.[30] I therefore conclude that upon providing adequate justification for the quantity of the importation, Lannett's registration would be consistent with the public interest.[31] 21 U.S.C. § 823(a).

Order

Lannett is hereby directed to file with this Office its testing protocol and an itemization setting forth the various quantities it needs to import for bioequivalency and stability studies, as well as reserves. If FDA requires that it import the entire batch that will be used for bioequivalency and stability testing and will not permit it to select its test samples from the production batch and import only those quantities, Lannett should provide evidence supporting this. Finally, if Lannett intends to pursue importation of the additional batches, it must provide additional justification for doing so. Lannett must serve a copy of all filings on the objectors. Lannett's submission shall be due no later than 90 days from date of the issuance of this Order; Lannett shall timely inform this Office of any delays in obtaining a response from FDA.[32] It is further ordered that Lannett's application for a registration to import dronabinol be held in abeyance.

Dated: November 15, 2012

Michele M. Leonhart

Administrator

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BILLING CODE 4410–09–P

[30] DEA has long held that it has authority to impose conditions on a registration. *See Alfred Khalily,* 64 FR 31289 (1999); *Gordon M. Acker, D.M.D.,* 53 FR 50309 (1988).

[31] Nor does the record establish any reason why granting Lannett's application would be inconsistent with the United States' obligations under international treaties and the Single Convention. *See Penick Corp.,* 491 F.3d at 492–93.

[32] The Objectors shall have thirty days from the date of receipt of Lannett's filing to submit a response.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

169th Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 169th open meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans (also known as the ERISA Advisory Council) will be held on November 4–5, 2013.

The meeting will take place in C5521 Room 4, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210 on November 4, from 1 p.m. to approximately 5:00 p.m. On November 5, the meeting will start at 8:30 a.m. and conclude at approximately 4:00 p.m., with a break for lunch. The morning session on November 5 will be in C5521 Room 1. The afternoon session on November 5 will take place in Room S–2508 at the same address. The purpose of the open meeting on November 4 and the morning of November 5 is for the Advisory Council members to finalize the recommendations they will present to the Secretary. At the November 5 afternoon session, the Council members will receive an update from the Assistant Secretary of Labor for the Employee Benefits Security Administration (EBSA) and present their recommendations.

The Council recommendations will be on the following issues: (1) Successful Retirement Plan Communications for Various Population Segments, (2) Locating Missing and Lost Participants, and (3) Private Sector Pension De-risking and Participant Protections. Descriptions of these topics are available on the Advisory Council page of the EBSA Web site at *http://www.dol.gov/ebsa/aboutebsa/erisa_advisory_council.html.*