(b) Affected Ads

None.

(c) Applicability

This AD applies to all The Boeing Company Model 717-200 airplanes, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by multiple reports of cracking in the overwing frames. We are issuing this AD to detect and correct such cracking, which could result in a severed frame and might increase the loading of adjacent frames, resulting in damage to the adjacent structure and consequent loss of structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspections and Corrective Actions

At the applicable time specified in paragraph (g)(1) or (g)(2) of this AD, do a general visual inspection and a high frequency eddy current (HFEC) inspection for cracking of the left-side and right-side overwing frames at station 737, and do all applicable corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 717–53A0036, dated August 12, 2013, except as required by paragraph (h)(3) of this AD. Do all applicable corrective actions before further flight. Except as required by paragraph (h)(2) of this AD, repeat the inspections thereafter at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 717–53A0036, dated August 12, 2013.

(1) For Group 1, Configuration 1 airplanes identified in Boeing Alert Service Bulletin 717–53A0036, dated August 12, 2013: At the time specified in table 1 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 717–53A0036, dated August 12, 2013, except as provided by paragraph (h)(1) of this AD.

(2) For Group 1, Configuration 2 airplanes identified in Boeing Alert Service Bulletin 717–53A0036, dated August 12, 2013: At the applicable time specified in paragraph (g)(2)(i) or (g)(2)(ii) of this AD.

(i) For airplanes on which the overwing frame has not been replaced: Within 9,300 flight cycles after accomplishing the inspections specified in Boeing Multi Operator Message (MOM) MOM–MOM–13–0375–01B, dated May 9, 2013.

(ii) For airplanes on which the overwing frame has been replaced: Within 12,000 flight cycles after replacing the frame.

(h) Exceptions to Service Information

(1) Where Boeing Alert Service Bulletin 717–53A0036, dated August 12, 2013, specifies a compliance time ''after the original issue date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where Boeing Alert Service Bulletin 717–53A0036, dated August 12, 2013, specifies to contact Boeing for the compliance time of an inspection repetitive interval, this AD requires a compliance time approved by the FAA in accordance with the procedures specified in paragraph (j) of this AD.

(3) Where Boeing Alert Service Bulletin 717–53A0036, dated August 12, 2013, specifies to contact Boeing for repair instructions, this AD requires repair before further flight using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Credit for Previous Actions

This paragraph provides credit for only the initial general visual inspection, HFEC inspection, and frame replacement required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Multi Operator Message (MOM) MOM–MOM–13–0375–01B, dated May 9, 2013.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and 14 CFR 25.571, Amendment 45, and the approval must specifically refer to this AD.

(4) If the service information contains steps that are labeled as RC (Required for Compliance), those steps must be done to comply with this AD; any steps that are not labeled as RC are recommended. Those steps that are not labeled as RC may be deviated from, done as part of other actions, or done using accepted methods different from those identified in the specified service information without obtaining approval of an AMOC, provided the steps labeled as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to steps labeled as RC require approval of an AMOC.

(k) Related Information

(1) For more information about this AD, contact: Eric Schrieber, Aerospace Engineer, Airframe Branch, ANM–120L, Los Angeles ACO, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5348; fax: 562–627–5210; email: *eric.schrieber@faa.gov.*

(2) For service information identified in this AD, Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; Internet *https://www.myboeingfleet.com.*

Issued in Renton, Washington, on November 26, 2013.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–29004 Filed 12–3–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2013–N–1524]

Bulk Drug Substances That May Be Used To Compound Drug Products in Accordance With Section 503B of the Federal Food, Drug, and Cosmetic Act, Concerning Outsourcing Facilities; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for nominations.

SUMMARY: The Food and Drug Administration (FDA or Agency) is preparing to develop a list of bulk drug substances (bulk drugs) that may be used to compound drug products in accordance with section 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), concerning outsourcing facilities. To identify candidates for this bulk drugs list, interested groups and individuals may nominate specific bulk drug substances, and FDA is describing the information that should be provided to the Agency in support of each nomination.

DATES: Submit either electronic or written nominations for the bulk drug substances list by March 4, 2014.

ADDRESSES: You may submit nominations, identified by Docket No. FDA–2013–N–1524, by any of the following methods.

Electronic Submissions

Submit electronic nominations in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written nominations in the following ways:

• *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–1524 for this request for nominations. All nominations received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting nominations, see the ''Request for Nominations'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or nominations received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marissa Chaet Brykman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Suite 5100, Silver Spring, MD 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Quality and Security Act (DQSA) adds a new section 503B to the FD&C Act (21 U.S.C. 353b) that creates a new category of ''outsourcing facilities.'' [1] Outsourcing facilities, as defined in section 503B of the FD&C Act, are facilities that meet certain conditions described in section 503B, including registering with FDA as an outsourcing facility. If these conditions are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from two sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and (2) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)); but not section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

One of the conditions in section 503B of the FD&C Act that must be satisfied to qualify for the exemptions is that an outsourcing facility does not compound using a bulk drug substance unless: (1) The bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, or the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing; (2) ''if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug [substance complies] with the monograph;'' (3) the bulk drug substance is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360); and (4) the bulk drug substance is accompanied by a valid certificate of analysis (see section 503B(a)(2) of the FD&C Act).

Section 503B of the FD&C Act refers to the definition of ''bulk drug substance'' in FDA regulations at 21 CFR 207.3(a)(4): ''any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances'' (see section 503B(a)(2)).

II. Request for Nominations

To identify candidates for this list, FDA is seeking public input in the form of specific bulk drug nominations. All interested groups and individuals may nominate specific bulk drug substances for inclusion on the list.

Nominations should include the following information about the bulk drug substance being nominated and the product(s) that will be compounded using such substance, and any other relevant information available. If the information requested is unknown or unavailable, that fact should be noted accordingly.

Bulk Drug Substance

- Ingredient name;
- Chemical name;
- Common name(s);
- Chemical grade or description of the strength, quality, and purity of the ingredient;
- Information about how the ingredient is supplied (e.g., powder, liquid);
- Information about recognition of the substance in foreign pharmacopeias and the status of its registration(s) in other countries, including whether information has been submitted to USP for consideration of monograph development;
- A bibliography of available safety and efficacy data,[2] including any relevant peer-reviewed medical literature; and
- An explanation of why there is a clinical need to compound from the bulk drug substance.

Compounded Product

- Information about the dosage form(s) into which the drug substance will be compounded (including formulations);
- Information about the strength(s) of the compounded product(s);
- Information about the anticipated route(s) of administration of the compounded product(s);
- Information about the past and proposed use(s) of the compounded product(s), including the rationale for its use or why the compounded product(s), as opposed to an FDA-approved product, is necessary; and
- Available stability data for the compounded product(s).

FDA cannot guarantee that all drugs nominated during the nomination period will be considered for inclusion on the next published bulk drugs list. Nominations received during the nomination period that are supported by the most complete and relevant information will likely be evaluated first. Nominations that are not evaluated during this first phase will receive consideration for list amendments, because the development of this list will be an ongoing process. Individuals and organizations also will be able to petition FDA to make additional list amendments after the list is published.

Interested persons may submit either electronic nominations to *http://www.regulations.gov* or written nominations to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of nominations. Identify nominations with the docket number found in brackets in the heading of this document. Received nominations may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday

[1] The DQSA also removes from section 503A of the FD&C Act the provisions that had been held unconstitutional by the U.S. Supreme Court in 2002. See *Thompson* v. *Western States Med. Ctr.,* 535 U.S. 357 (2002).

[2] FDA recognizes that the available safety and efficacy data supporting consideration of a bulk drug substance for inclusion on the list may not be of the same type, amount, or quality as is required to support an NDA.

through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28978 Filed 12–2–13; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2013–N–1523]

Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for nominations.

SUMMARY: The Food and Drug Administration (FDA or Agency) is preparing to develop a list of drug products that present demonstrable difficulties for compounding (difficult-to-compound list). To identify candidates for this list, FDA is encouraging interested groups and individuals to nominate specific drug products or categories of drug products and is describing the information that should be provided to the Agency in support of each nomination.

DATES: Submit written or electronic comments by March 4, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–1523, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• *Mail/Hand delivery/Courier [for paper submissions]:* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–1523 for this request for nominations. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Request for Nominations'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marissa Chaet Brykman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, suite 5100, Silver Spring, MD 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions under which a human drug product compounded for an identified individual patient based on a prescription is entitled to an exemption from three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

One of the conditions for such an exemption is that the compounded drug product is not a ''drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product'' (section 503A(b)(3)(A) of the FD&C Act).

Section 503A(d)(1) of the FD&C Act requires that before issuing regulations to implement section 503A(b)(3)(A) of the FD&C Act, an advisory committee on compounding be convened and consulted ''unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health'' (section 503A(d)(1) of the FD&C Act).

At a meeting on July 13 and 14, 2000, the Pharmacy Compounding Advisory Committee discussed and provided FDA with advice about the Agency's efforts to develop a list of drugs that present demonstrable difficulties for compounding. FDA had published a notice of that meeting in the **Federal Register** of June 29, 2000 (65 FR 40104). However, before a list could be developed, the constitutionality of section 503A was challenged in court because it included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug and the solicitation of prescriptions for compounded drugs. These provisions were held unconstitutional by the U.S. Supreme Court in 2002.[1] After the court decision, FDA suspended its efforts to develop the difficult-to-compound list.

The Drug Quality and Security Act (DQSA) removes from section 503A of the FD&C Act the provisions that had been held unconstitutional by the U.S. Supreme Court in 2002. By removing these provisions, the new law removes uncertainty regarding the validity of section 503A, clarifying that it applies nationwide. Therefore, FDA is reinitiating its efforts to develop a list of drug products that present demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product.

In addition, the DQSA adds a new section 503B to the FD&C Act (21 U.S.C. 353b) that creates a new category of ''outsourcing facilities.'' Outsourcing facilities, as defined in section 503B, are facilities that meet certain conditions described in section 503B, including registering with FDA as an outsourcing facility. If these conditions are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from two sections of the FD&C Act: (1) Section 502(f)(1) and (2) section 505; but not section 501(a)(2)(B).

One of the conditions in section 503B that must be satisfied to qualify for the exemptions is that an outsourcing facility does not compound a drug identified (directly or as part of a category of drugs) on a list published by the Secretary of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients, or the drug is compounded in

[1] See *Thompson* v. *Western States Med. Ctr.,* 535 U.S. 357 (2002).