$30 million (including all affiliates, partners, and parent firms), they will also qualify for a waiver of the fee for their first (ever) premarket application, product development protocol, biological licensing application, or premarket report. A ''small business'' is eligible for reduced or waived fees. If an applicant does not provide information to FDA demonstrating to FDA's satisfaction that the applicant is a small business, the applicant must pay the standard (full) fee for any application it submits.

Forms FDA 3602 (''MDUFA Small Business Certification Request for a Business Headquartered in the United States'') and 3602A (''MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States'') are submitted to FDA to demonstrate that an applicant qualifies as a MDUFA small business. The guidance ''Medical Device User Fee Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' [1] describes the process by which a business may request certification as a small business and the criteria FDA will use to decide whether an entity qualifies as a MDUFA small business and is eligible for a reduction in user fees.

In the **Federal Register** of December 23, 2021 (86 FR 72983), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, however it did not respond to the functional elements solicited in our 60-day notice or suggest a revision to our burden estimate.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3602—MDUFA Small Business Certification Request For a Business Headquartered in the United States	2,500	1	2,500	1	2,500
FDA 3602A—MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States	2,000	1	2,000	1	2,000
Total					4,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden is based on the number of applications received in the last few years and includes the time we assume necessary to prepare and submit required information. Based on our experience with Forms FDA 3602 and 3602A, we assume it will take respondents 1 hour to complete either form. We have adjusted our estimated ''No. of Respondents'' to better reflect recent submission volume. This adjustment results in a 2,500-hour decrease to the information collection.

Dated: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08726 Filed 4–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1975–N–0336 (formerly 1975N–0184)]

Drugs for Human Use; Drug Efficacy Study Implementation; Oral Prescription Drugs Containing an Anticholinergic or Antispasmodic in Combination With a Sedative, and Single-Entity Antispasmodic Drug Products, in Oral Dosage Form; Withdrawal of Hearing Requests; Final Resolution of Drug Efficacy Study Implementation

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that all outstanding hearing requests regarding drug products containing an anticholinergic or antispasmodic in combination with a sedative, and single-entity antispasmodic drug products, in oral dosage form, under Docket FDA–1975–N–0336 (formerly 75N–0184) (DESI 10837) have been withdrawn. Therefore, shipment in interstate commerce of any such product identified in Docket FDA–1975–N–0336 covered by DESI 10837, or any identical, related, or similar (IRS) product, that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) is unlawful as of the date of this notice. This notice does not affect products covered by DESI 597 under the same docket.

DATES: This notice is applicable April 25, 2022.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The most relevant background documents regarding this matter are available in the docket. However, additional background documents are available upon request (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Jeffrey Trunzo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5111,

[1] The guidance ''Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification.*

Silver Spring, MD 20993–0002, 301–796–2029, email: *Jeffrey.Trunzo@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

When enacted in 1938, the Federal Food, Drug, and Cosmetic Act (FD&C Act) required that ''new drugs'' (21 U.S.C. 321(p)) be approved for safety by FDA before they could legally be sold in interstate commerce. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were IRS (see 21 CFR 310.6(b)(1)) to the approved drug to be covered by that approval and allowed those IRS drugs to be marketed without independent approval.

In 1962, Congress amended the FD&C Act to require that new drugs be proven effective for their labeled indications, as well as safe, in order to obtain FDA approval. This amendment also required FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The Agency reviewed and reevaluated the reports and published its findings in **Federal Register** notices. FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.

All drugs covered by the DESI review are ''new drugs'' under the FD&C Act. If FDA's final DESI determination classifies a drug product as lacking substantial evidence of effectiveness for one or more indications, that drug product and those IRS to it may no longer be marketed for such indications and are subject to enforcement action as unapproved new drugs. If FDA's final DESI determination classifies the drug product as effective for one or more of its labeled indications, the drug can be marketed for such indications, provided it is the subject of an application approved for safety and effectiveness. Sponsors of drug products that have been found to be effective for one or more indications through the DESI process may rely on FDA's effectiveness determinations, but typically must update their labeling to conform to the indication(s) found to be effective by FDA and include any additional safety information required by FDA. Those drug products with NDAs approved before 1962 for safety therefore require approved supplements to their original applications if one or more indications are found to be effective under DESI; IRS drug products require an approved NDA or ANDA, as appropriate. Furthermore, labeling for drug products classified as effective may contain only those indications for which the review found the product effective unless the firm marketing the product has received an approval for the additional indication(s).

II. Final Resolution of Hearing Requests Regarding Oral Prescription Drugs Containing an Anticholinergic or Antispasmodic in Combination With a Sedative, and Single-Entity Antispasmodic Drug Products, in Oral Dosage Form Under Docket No. FDA–1975–N–0336 (Formerly 75N–0184); DESI 10837

In a **Federal Register** notice published on June 22, 1971 (36 FR 11875) (1971 **Federal Register** notice), FDA announced its evaluation of reports received from NAS/NRC under DESI 10837, regarding anticholinergic drug products containing the following active ingredients: Prochlorperazine maleate and isopropamide iodide; oxyphencyclimine hydrochloride and meprobamate; oxyphencyclimine hydrochloride and hydroxyzine hydrochloride; tridihexethyl chloride and meprobamate; and propantheline bromide and thiopropazate hydrochloride. The drugs were found to be possibly effective as adjunctive therapy in peptic ulcer and in the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis, functional gastrointestinal disorders); functional diarrhea; drug induced diarrhea; ulcerative colitis, and urinary bladder spasm, and urethral spasm (*i.e.,* smooth muscle spasm). In addition, oxyphencyclimine and meprobamate preparations were found to be possibly effective for dysmenorrhea. These drugs were found to lack substantial evidence of effectiveness for their other labeled indications.

In a **Federal Register** notice published November 11, 1975 (40 FR 52644) (1975 **Federal Register** notice), the Agency explained that several of the products listed in the 1971 **Federal Register** notice may remain on the market while clinical studies were being conducted to determine their efficacy for the indications rated as ''possibly effective,'' because they were widely used in the treatment of peptic ulcer disease and functional bowel syndrome and were perceived as important and useful tools of therapy by many gastroenterologists and general practitioners (40 FR 52644 at 52648). In addition to the products from the 1971 **Federal Register** notice, the 1975 **Federal Register** notice included several products, among them Librax Capsules, NDA 12–750, containing clidinium bromide and chlordiazepoxide, now manufactured by Bausch Health Companies, Inc. (Bausch), that had been the subject of safety-only applications approved before 1962 and that had not been reviewed by NAS/NRC. Librax Capsules was included in the 1975 **Federal Register** notice notwithstanding the Stipulation for Dismissal in *Hoffman-La Roche, Inc.* v. *Richardson, et. al.,* Civil Action 11–73 (D.N.J. August 2, 1973), discussed below. The 1975 **Federal Register** notice set forth a timetable for conducting clinical efficacy studies for drug products subject to the notice. In a **Federal Register** notice published June 20, 1978 (43 FR 26490) (1978 **Federal Register** notice), FDA announced a change in its previous policy for testing and marketing of the drugs that were subject of the November 11, 1975, notice (*e.g.,* Librax), including an extension of deadline for completion of the studies for 1 year.

In a **Federal Register** notice published January 16, 1981(46 FR 3977) (1981 **Federal Register** notice), FDA announced its evaluation of study reports received in response to the 1975 **Federal Register** notice. FDA concluded that there was a lack of substantial evidence demonstrating the effectiveness of the drugs listed in the 1975 notice, proposed to withdraw approval of the new drug applications, and offered an opportunity for hearing to manufacturers of the drugs listed in the notice, as well as to the manufacturers of IRS products.

As set forth in a **Federal Register** notice published July 24, 2012 (77 FR 43337) (2012 **Federal Register** notice), several companies submitted timely hearing requests in response to the 1981 **Federal Register** notice, but the only such request that had not been withdrawn as of July 2012, was the request regarding Librax Capsules, filed by Roche Laboratories, manufacturer of Librax Capsules in 1981 (77 FR 43337 at 43341). In response to the 2012 **Federal Register** notice, Valeant Pharmaceuticals North America LLC (now Bausch) affirmed the hearing request regarding Librax Capsules by letter dated August 22, 2012.

On May 23, 2016, FDA posted a Notice to Docket 1975–N–0336,

explaining that Librax is not subject to review under DESI because a new drug application for Librax was approved by the Agency on September 1, 1966, and at that time the Agency determined that Librax was safe and effective for the indications set forth in its labeling, (consistent with the Stipulation for Dismissal in *Hoffman-La Roche, Inc.* v. *Richardson, et al.,* Civil Action 11–73 (D.N.J. August 2, 1973)). On June 2, 2016, Valeant responded by withdrawing its hearing request.

There are no longer outstanding hearing requests pertaining to drug products containing an anticholinergic or antispasmodic in combination with a sedative, and single-entity antispasmodic drug products, in oral dosage form under Docket No. FDA–1975–N–0336, DESI 10837. Shipment in interstate commerce of any drug product identified in this docket under DESI 10837, or any IRS product, that is not the subject of an approved NDA or ANDA is unlawful as of the applicable date of this notice (see **DATES**). Any person who wishes to determine whether a specific product is covered by this notice should write to Jeffrey Trunzo (see **FOR FURTHER INFORMATION CONTACT**). Firms should be aware that, after the applicable date of this notice (see **DATES**), FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice.

III. Discontinued Products

Firms must notify the Agency of certain product discontinuations in writing under section 506C(a) of the FD&C Act (21 U.S.C. 356c) (see *https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm*). Some firms may have previously discontinued manufacturing or distributing products covered by this notice without discontinuing the listing as required under section 510(j) of the FD&C Act (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or distributing listed products in response to this notice. All firms are required to electronically update the listing of their products under 510(j) of the FD&C Act to reflect discontinuation of unapproved products covered by this notice (21 CFR 207.57(b)). Questions on electronic drug listing updates should be sent to *eDRLS@fda.hhs.gov.* In addition to the required update, firms can also notify the Agency of product discontinuation by sending a letter, signed by the firm's chief executive officer and fully identifying the discontinued product(s), including the product National Drug Code (NDC) number(s), and stating that the manufacturing and/or distribution of the product(s) have been discontinued. The letter should be sent electronically to Jeffrey Trunzo (see **FOR FURTHER INFORMATION CONTACT**). FDA plans to rely on its existing records, including its drug listing records, the results of any future inspections, or other available information, when it identifies violative products for enforcement action.

IV. Reformulated Products

FDA cautions firms against reformulating products and marketing under the same name or substantially the same name (including a new name that contains the old name). Reformulated products marketed under a name previously identified with a different active ingredient or combinations of active ingredients have the potential to confuse healthcare practitioners and harm patients.

Dated: April 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08740 Filed 4–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0081]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled ''Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion.''

DATES: Submit either electronic or written comments on the collection of information by June 24, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 24, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 24, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–N–0081 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Tradeoff Analysis of Prescription Drug Product