Evaluation and Research and Center for Biologics and Research committed to further our efforts to enhance benefit-risk assessment and communication in the human drug review process in FY 2013–2017. Enhancing and communicating benefit-risk assessment continues to be an Agency priority in PDUFA VI. The draft plan describes the progress made on PDUFA V in benefit-risk assessment. This progress includes revision of FDA's review/decision templates and manuals to incorporate FDA's approach to benefit-risk assessment, training review and management of staff on the revised templates and manuals, developing an evaluation plan to ascertain the impact of FDA's implementation of the Benefit-Risk Framework in drug review, holding two public workshops on benefit-risk considerations from the regulator's perspective, and advancing FDA's Patient-Focused Drug Development initiative. This draft plan also summarizes the third-party evaluation of FDA's implementation of the Benefit-Risk Framework into FDA's new drug review.

The plan also includes an overview of FDA's commitments in PDUFA VI for continued implementation of structured benefit-risk assessment during FY 2018–2022. These commitments include participating in a meeting to gather stakeholder input on key topics, publishing a draft guidance on benefit-risk assessment for new drugs and biologics, continuing to revise relevant Manuals for Policies and Procedures and Standard Operating Practices and Procedures to incorporate benefit-risk assessment approaches, and conducting a second evaluation of the implementation of the Benefit-Risk Framework beginning in 2021. In addition to these commitments, FDA also plans to explore additional opportunities to enhance our use and communication of benefit-risk assessments.

III. Electronic Access

FDA has published the draft plan on its website: *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.* The period for public comment on the draft plan will remain open for 60 days following the publication of this notice. After consideration of public comments, FDA will finalize the plan. Throughout PDUFA VI, the Agency will update the plan as necessary and post all updates on FDA's website.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06531 Filed 3–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0369]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements of our regulations implementing the Federal Import Milk Act (FIMA).

DATES: Submit either electronic or written comments on the collection of information by June 1, 2018.

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 1, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 1, 2018. 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–2012–N–0369 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations under the Federal Import Milk Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: 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, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations Under the Federal Import Milk Act (FIMA)—21 CFR Part 1210

OMB Control Number 0910–0212—Extension

Under FIMA (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F (21 U.S.C. 142).

Our regulations in part 1210 (21 CFR part 1210), implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms and plants producing milk and/or cream to be shipped to the United States. Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of tuberculin testing of the herds. In addition, the regulations in part 1210 require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper. Section 1210.23 allows permits to be granted based on certificates from accredited officials.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1210.11	1996/Farm Inspection Report	2	200	400	1.5	600
1210.12	1995/Report of Physical Examination of Cows.	1	1	1	.5 (30 minutes)	.5
1210.13	1994/Report of Tuberculin Tests of Cattle	1	1	1	.5 (30 minutes)	.5
1210.14	1997/Score Card for Sanitation Inspections of Milk Plants.	2	1	2	2	4
1210.20	1993/Application for Permit to Ship or Transport Milk and/or Cream into US.	2	1	2	.5 (30 minutes)	1
1210.23	1815/Certificate/Transmittal for an Application.	2	1	2	.5 (30 minutes)	1
Total	.....	.....	.....	.....	.....	607

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1210.15	2	1	2	.05 (3 minutes)	.10 (6 minutes)

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

Upon review of the information collection, we have retained the currently approved estimated burden. The estimated number of respondents and hours per response are based on our experience with the import milk permit program and the average number of import milk permit holders over the past 3 years. Assuming two respondents will submit approximately 200 Form FDA 1996 reports annually for a total of 600 responses, and that each response requires 1.5 hours, we estimate the total burden is 600 hours.

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms. Because we have not received any Forms FDA 1994 or 1995 in the last 3 years, we assume no more than one will be submitted annually. We also assume each submission requires 0.5 hour for a total of 0.5 burden hour annually.

We estimate that two respondents will submit one Form FDA 1997 report annually, for a total of two responses. We estimate the reporting burden to be 2.0 hours per response, for a total burden of 4 hours. We estimate that two respondents will submit one Form FDA 1993 report annually, for a total of two responses. We estimate the reporting burden to be 0.5 hour per response, for a total burden of 1 hour. We estimate that two respondents will submit one Form FDA 1815 report annually, for a total of two responses. We estimate the reporting burden to be 0.5 hour per response, for a total burden of 1 hour.

With regard to records maintenance, we estimate that approximately two recordkeepers will spend 0.05 hour annually maintaining the additional pasteurization records required by § 1210.15, for a total of 0.10 hour annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by us (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of business activities.

Dated: March 27, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06595 Filed 3–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0549]

Prescription Polyethylene Glycol 3350; Denial of a Hearing and Order Withdrawing Approval of Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs (the Commissioner) is denying requests for a hearing and issuing an order withdrawing approval of abbreviated new drug applications (ANDAs) for certain prescription laxatives with the active ingredient polyethylene glycol 3350 (PEG 3350), listed in this document, because the drug products are misbranded under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This order is applicable May 2, 2018.

ADDRESSES: For access to the docket, 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, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Scientific Integrity, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993–0002, 301–796–8618.

SUPPLEMENTARY INFORMATION:

I. Background

A. Procedural Background

On February 18, 1999, the U.S. Food and Drug Administration (FDA or the Agency) approved a new drug application (NDA) submitted by Braintree Laboratories, Inc., (Braintree) for prescription (or ''Rx'') PEG 3350 (MiraLAX) (NDA 20–698). Subsequently, FDA approved five ANDAs for prescription PEG 3350.[1] On October 6, 2006, FDA approved a new NDA (NDA 22–015) submitted by Braintree, removing their PEG 3350 laxative drug product from prescription dispensing requirements of section 503(b) of the FD&C Act (21 U.S.C. 353(b)).[2]

Section 503(b)(1) of the FD&C Act requires that a drug which: (1) Because

[1] The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) created new section 505(j) of the FD&C Act, which established the current ANDA approval process. To obtain approval, an ANDA applicant is not required to submit evidence to establish the clinical safety and effectiveness of the drug product; instead, an ANDA relies on FDA's previous finding that the reference listed drug is safe and effective. To rely on a previous finding of safety and effectiveness, an ANDA applicant must demonstrate, among other things, that the drug product described in an ANDA has the same active ingredient(s), indications for use, route of administration, dosage form, strength, and labeling as the reference listed drug (section 505(j)(2)(A)(i)–(v) and (j)(4) of the FD&C Act). In addition, the ANDA applicant must submit evidence that its proposed drug product is bioequivalent to the reference listed drug (section 505(j)(2)(A)(iv) of the FD&C Act).

[2] On October 10, 2008, Braintree requested that FDA withdraw approval of the NDA for prescription MiraLAX (NDA 20–698) under 21 CFR 314.150(c) because it had stopped marketing the product. On February 11, 2009, FDA withdrew approval of the NDA for prescription MiraLAX in a **Federal Register** notice (effective March 13, 2009)(74 FR 6896 at 6899 (February 11, 2009)).