TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturers of an Unapproved EUA Product	12	2	24	25	600
Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					870

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

Our estimated annual reporting burden for the information collection reflects an overall increase of 239 hours since our last request for OMB approval. We attribute this adjustment to an increase in the number of submissions we received.

Dated: March 29, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06553 Filed 4–3–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 6, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs—OMB Control Number 0910–NEW

This information collection request supports recommendations found in the Agency guidance document entitled, ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' The guidance document outlines the requirements and recommendations for manufacturers, packers, and distributors (firms) that may either be the applicant or acting on behalf of the applicant, to make submissions pertaining to promotional materials for human prescription drugs (''drugs'') to the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) and the Advertising and Promotional Labeling Branch (APLB) in the Center for Biologics Evaluation and Research (CBER). References to ''drugs'' in the guidance also include human biological products that fall within the definition of ''drug'' under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(g)).

The guidance describes the various types of submissions of promotional materials and general considerations for submissions. The guidance discusses the specific aspects of submission of promotional materials using module 1 of the electronic Common Technical Document (eCTD) using version 3.3 or higher of the *us-regional-backbone* file. The guidance does not address the more general requirements for a valid electronic submission using eCTD or the specifications for module 1 of the eCTD. The guidance contains both binding and nonbinding provisions. The provisions that are binding implement section 745A(a) of the FD&C Act (21 U.S.C. 379k–1(a)), which requires that certain submissions be submitted in electronic format specified by FDA, beginning no earlier than 24 months after FDA issues a final guidance specifying such electronic submission format.

The guidance provides recommendations for what to include with each type of submission and the number of copies to include if it is a paper submission. For promotional labeling submitted for advisory comments, including resubmissions, a submission generally includes correspondence stating that it is a request for advisory comments, a clean version of the draft promotional materials, an annotated copy of the promotional materials, and the most current FDA-approved prescribing information (PI); if applicable, a submission also includes the FDA-approved patient labeling or Medication Guide with annotations cross-referenced to the proposed promotional materials and annotated references to support product and disease or epidemiology claims not contained in the PI cross-referenced to the promotional material. Amendments should be submitted if the previous submission to FDA is missing one or more promotional materials or if an incorrect document file was included with a submission in eCTD format. Amendments should include correspondence stating it is an amendment and include the accompanying materials that were previously missing, an annotated copy of the promotional materials that were omitted from a previous submission to FDA, the FDA-approved patient labeling or Medication Guide with annotations

cross-referenced to the proposed promotional materials, and annotated references to support product and disease or epidemiology claims not contained in the PI cross-referenced to the promotional material.

General correspondence submissions and submissions requesting to withdraw a previous submission to FDA include correspondence stating the purpose of the submission.

Responses to untitled or warning letter submissions include correspondence stating that it is a response to an untitled or warning letter, and include the firm's initial or subsequent responses and the corrective piece(s), if applicable.

Responses to information request submissions include the firm's response to the questions and issues raised in FDA's letter of inquiry, including any materials that FDA has requested.

Reference document submissions include correspondence stating that it is a reference document submission and the specific information regarding what is in the submission along with the annotated references, annotated promotional materials, and/or annotated labeling.

Promotional labeling submitted for advisory comments, including resubmissions and amendments; general correspondence; requests to withdraw a previous submission; responses to untitled or warning letters; responses to information requests; and reference documents can be submitted in paper or electronic form, and the burden estimates for these submissions in table 1 apply to both paper and electronic form.

Complaints include correspondence stating that it is a complaint and supporting information or documentation, if available. Complaints are not accepted in electronic form and should be submitted as paper copies. The burden estimate for complaints in table 1 thus applies to paper copies only.

The guidance also describes the number of paper copies that should be sent to OPDP and APLB for each submission type (if applicable).

The guidance provides recommendations for presentation considerations such as appearance, layout, format, and visible impression of promotional materials submitted for all promotional submission types.

The guidance also provides instructions on how to submit promotional labeling and advertising materials to FDA electronically in eCTD format. It explains that for submissions of promotional materials that fall within the ambit of section 745A(a) of the FD&C Act (21 U.S.C. 379k–1(a)), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), such submissions must be made in the electronic format specified by FDA in the guidance, beginning no earlier than 24 months after the guidance is finalized. Specifically, (1) postmarketing submissions of promotional materials using Form FDA 2253 (required by 21 CFR 314.81(b)(3)(i) and 601.12(f)(4)), and (2) submissions of promotional materials for accelerated approval products (required by FD&C Act section 506(c)(2)(B) (21 U.S.C. 356(c)(2)(B)), and 21 CFR 314.550 and 601.45) and other products where such submissions are required for approval, fall within the scope of section 745A(a) and are, therefore, subject to the mandatory electronic submission requirement.

When the mandatory electronic submission requirement takes effect for these types of submissions, they will be accepted by CDER only in eCTD format using version 3.3 or higher of the *us-regional-backbone* file. CBER will be able to accept eCTD submissions using previous versions of the *us-regional-backbone* file until 24 months after publication of the guidance. The guidance also provides that, while only promotional submissions that fall under section 745A(a) will be required to be submitted electronically no sooner than 24 months after the guidance is finalized, firms are strongly encouraged, but not required, to submit electronically the other types of promotional submissions discussed in the guidance.

In the **Federal Register** of April 22, 2015 (80 FR 22529), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received requesting clarification on the submission of annotated versions of promotional materials for Form FDA 2253 submissions. We appreciate the comment and have revised the guidance to further clarify that annotated versions of promotional materials are encouraged, not required. The guidance was also revised to encourage the submission of a CD copy of paper submissions and burden estimates have been updated accordingly. Any increase in burden is expected to be nominal.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of submission	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Promotional labeling submitted for advisory comments, including resubmissions and amendments	76	13	1,024	51	52,224
General correspondence submitted to FDA	84	4	359	3	1,077
Requests to withdraw a previous submission to FDA	15	1	22	3	66
Responses to untitled or warning letters	7	2	13	13	169
Responses to information requests	6	1	3	13	39
Reference documents	7	2	14	13	182
Complaints submitted to FDA	82	1	117	13	1,521
Total					55,278

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

Our estimate is based on our experience with the submission of labeling materials for human prescription drugs. Because this is a new collection of information, we are specifically interested in receiving comments from respondents to the information collection regarding our burden estimate.

Dated: March 29, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06565 Filed 4–3–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–3883]

Determination That CORTISPORIN (Hydrocortisone/Neomycin Sulfate/Polymyxin B Sulfate) Otic Solution, 10 Milligrams/Milliliter Hydrocortisone, 3.5 Milligrams Base/Milliliter Neomycin Sulfate, 10,000 Units/Milliliter Polymyxin B Sulfate, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 milligrams (mg)/milliliter (mL) hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Kate Greenwood, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6286, Silver Spring, MD 20993–0002, 240–402–1748.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, is the subject of NDA 050479, held by Monarch Pharmaceuticals LLC, and initially approved on December 9, 1975. CORTISPORIN is indicated for the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics.

CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Foley & Lardner LLP submitted a citizen petition dated October 11, 2018 (Docket No. FDA–2018–P–3883), under § 10.30 (21 CFR 10.30), requesting that the Agency determine whether CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs.

If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.