DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–P–1896]

Determination That OXYTOCIN in 5% Dextrose Injection Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 OXYTOCIN 5 United States Pharmacopeia (USP) Units in Dextrose 5% (oxytocin), injectable, injection, 5 USP Units in 500 milliliters (mL), (1 USP Unit/100 mL); OXYTOCIN 10 USP Units in Dextrose 5% (oxytocin), injectable, injection, 10 USP Units in 500 mL, (2 USP Units/100 mL); OXYTOCIN 10 USP Units in Dextrose 5% (oxytocin), injectable, injection, 10 USP Units in 1000 mL, (1 USP Unit/100 mL); and OXYTOCIN 20 USP Units in Dextrose 5% (oxytocin), injectable, injection, 20 USP Units in 1000 mL, (2 USP Units/100 mL), (hereinafter ''these oxytocin drug products'') were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve an abbreviated new drug application (ANDA) for these oxytocin drug products, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Robin Fastenau, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 240–402–4510.

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.

These oxytocin drug products are the subject of NDA 019–185, held by Abbott Laboratories, and initially approved on March 29, 1985. These oxytocin drug products are indicated for the initiation or improvement of uterine contractions. In a December 26, 1995, letter, Abbott Laboratories notified FDA that these oxytocin drug products were being discontinued and requested withdrawal of NDA 019–185. In the **Federal Register** of March 27, 1996 (61 FR 13506), FDA announced that it was withdrawing approval of NDA 019–185, effective April 26, 1996. FDA has moved these oxytocin drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

TechReg Services, Inc. (TechReg), submitted a citizen petition dated November 12, 2014 (Docket No. FDA–2014–P–1896), under 21 CFR 10.30, requesting that the Agency determine whether Oxytocin in Dextrose 5%, injection, available as strengths 5, 10, and 20 units under Abbott NDA 019–185, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not specify the concentrations of the three strengths associated with NDA 019–185, we have considered whether any of these oxytocin drug products approved under NDA 019–185 were withdrawn for safety or effectiveness reasons.

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 these oxytocin drug products were not withdrawn for reasons of safety or effectiveness. TechReg has identified no data or other information suggesting that these oxytocin drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of these oxytocin drug products 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 these oxytocin drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list these oxytocin drug products 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. ANDAs that refer to these oxytocin drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. FDA has determined that labeling for these oxytocin drug products should be revised to meet current standards and will advise ANDA applicants how to submit such labeling.

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–09299 Filed 4–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1163]

Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs, Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' This draft guidance explains how manufacturers, packers, and distributors (firms) that may either be the applicant or acting on

behalf of the applicant, should make submissions pertaining to promotional materials for human prescription drugs and biologic products (''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). This draft guidance describes the various types of submissions of promotional materials and general considerations for submissions. In addition, this draft 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. This guidance does not address the more general requirements for a valid electronic submission using eCTD or the specifications for module 1 of the eCTD. This guidance contains both binding and nonbinding provisions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 21, 2015. Submit either electronic or written comments on the proposed collection of information by June 22, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding human prescription drugs: Marci Kiester, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3368, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding prescription human biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' This draft guidance is intended to be used in conjunction with the draft guidance for industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' [1] (eCTD Revised Draft Guidance) and in conjunction with the specification to industry ''The eCTD Backbone Files Specification for Module 1 Version 2.3.'' [2]

This draft guidance describes various types of regulatory submissions of promotional materials that firms submit to CDER and CBER and general considerations for such submissions. For example, the draft guidance describes the various types of voluntary submissions (*e.g.,* launch and non-launch voluntary submissions of draft promotional materials for advisory comments) and required submissions of promotional labeling and advertising materials (*e.g.,* fulfillment of the regulatory requirements for postmarketing submissions of promotional materials and submission of promotional materials for accelerated approval products). In addition, this draft guidance discusses specific aspects of the content and format for submitting promotional materials in paper hard copy and electronic format, including how to submit promotional materials electronically in module 1 of the eCTD using version 3.3 or higher of the *us-regional-backbone* file. This draft 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. This draft guidance provides recommendations for presentation considerations such as appearance, layout, format, and visible impression of promotional materials submitted for all promotional submission types.

This draft 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, 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 this guidance and the eCTD Revised Draft Guidance, beginning no earlier than 24 months after this guidance is finalized. Specifically, (1) postmarketing submissions of promotional materials using Form FDA 2253 (required by 21 CFR 314.81(b)(3)(i) and 21 CFR 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 §§ 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 only be accepted by CDER 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 final version of this guidance. The draft 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 this guidance is finalized, firms may choose—and are strongly encouraged—to submit electronically the other types of promotional submissions discussed in this guidance.

This draft guidance is being issued under section 745A(a) of the FD&C Act, which explicitly authorizes FDA to implement the statutory electronic submission requirement for certain types of submissions by specifying the format for such submissions in guidance. Accordingly, to the extent that the draft guidance provides such requirements under section 745A(a), it

[1] The draft guidance for industry is available on the FDA eCTD Web page at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf.*

[2] The specification for industry is available on the FDA eCTD Module 1 Web page at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm.*

is not subject to the usual restrictions in FDA's good guidance practices regulation (21 CFR 10.115). However, to the extent that the draft guidance includes provisions regarding submission of promotional materials that do not pertain to the electronic format requirements for submissions under section 745A(a), it will represent the Agency's current thinking on the submission of promotional materials and will not create or confer any rights for or on any person or bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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.

Title: *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*

Description of Respondents: Respondents to this collection of information are firms who make regulatory submissions pertaining to promotional materials for human prescription drug and biologic products to OPDP and APLB.

Burden Estimate: The draft guidance pertains to regulatory submissions of promotional materials. The draft guidance describes the types of submissions of promotional materials, general considerations for submissions, and certain considerations for how to submit promotional materials electronically and in hard copy.

The draft guidance includes recommendations for when sponsors make submissions to OPDP or APLB. These recommendations include the types of documents that generally should be included (*e.g.,* correspondence describing the type of submission) for promotional labeling submitted for advisory comments, resubmissions, general correspondence, amendments, withdrawal requests, responses to untitled letters or warning letters, responses to information requests, reference documents, and complaints.

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. 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 hard copies. The burden estimate for complaints in table 1 thus applies to paper hard copies only.

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

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

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	199	2.5	499	50	24,950
General correspondence submitted to FDA	200	2.5	500	2	1,000
Requests to withdraw a previous submission to FDA	6	1	6	2	12
Responses to untitled or warning letters	26	2	52	12	624
Responses to information requests	4	1.5	6	12	72
Reference documents	7	1	7	12	84
Complaints submitted to OPDP	60	1	60	12	720
Total					27,462

This draft guidance also refers to previously approved collections of information found in FDA regulations and collections of information that are currently under OMB review. The collections of information in 21 CFR 202.1, including requests for advisory comments, resubmissions, and amendments for advertisements, have been approved under OMB control number 0910–0686; the collections of information in 21 CFR 601.45 (presubmission of promotional materials for accelerated approval products under part 601) have been approved under OMB control number 0910–0338; the collections of information for FDA Form 2253 and the presubmission of promotional materials for accelerated approval products under part 314 have been approved under OMB control number 0910–0001. FDA has also published in the **Federal Register** a 60-day notice soliciting public comments on the collections of information that result from the submission of television advertisements under section 503C of the FD&C Act (21 U.S.C. 353c) (77 FR 14811, March 13, 2012). These burden estimates do not change as a result of this guidance. This is because new burdens for establishing the means for submitting materials in electronic form to comply with this guidance would be negated by the savings in burden from not having to print out the materials and mail them to FDA.

Some firms may incur costs associated with upgrading technology or changing the method of submitting information to FDA, and these have been described in the **Federal Register** notice for the revised draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications'' (79 FR 43494, July 25, 2014).

III. Comments

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

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–09297 Filed 4–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0093]

Interim Assessment of the Program for Enhanced Review Transparency and Communication; Public Meeting and Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to obtain comments on the interim assessment of the Program for Enhanced Review Transparency and Communication for New Molecular Entity (NME) New Drug Applications (NDAs) and Original Biologics License Applications (BLAs) (the Program). FDA is also announcing a public meeting where the interim assessment will be discussed and public stakeholders may present their views on the Program to date.

The Program is part of the FDA performance commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA), which enables FDA to collect user fees for the review of human drug and biologics applications for fiscal years (FYs) 2013–2017. The Program is described in detail in section II.B entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017.'' The Program is being evaluated by an independent contractor with expertise in assessing the quality and efficiency of pharmaceutical and biopharmaceutical development and regulatory review programs. As part of FDA's performance commitments, FDA is providing a period for public comment on the interim assessment of the Program.

DATES: See Section III, ''How to Participate in the Public Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meeting, closing dates for advance registration, requesting special accommodations due to disability, and information on deadlines for submitting either electronic or written comments to FDA's Division of Dockets Management.

ADDRESSES: See Section III, ''How to Participate in the Public Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document.