(section 121(c)) by developing appropriate procedures for the approval of PET drugs in accordance with section 505 of the FD&C Act (21 U.S.C. 355) and to establish current good manufacturing practice requirements for PET drugs. Within FDAMA, Congress recognized the unique characteristics of PET drugs—in particular, the special criteria and processes required to produce these drugs—directing the Secretary of Health and Human Services to take due account of any relevant differences between not-for profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. See section 121(c)(1)(B) of FDAMA.

Statements like this indicate that one of Congress' goals in enacting section 121 of FDAMA was to promote the availability of FDA-approved PET drug products for the patients who need them. Previously, FDA found that, because of the unique circumstances surrounding the regulation of PET drug products, assessment of an application fee on certain PET drugs would present a significant barrier to innovation, and FDA granted a waiver of application fees for certain PET drug products.[1] Similarly, FDA believes that the requirement to submit applications in eCTD format could result in a significant burden on certain PET drug producers and may lead to reduced availability of these innovative and lifesaving diagnostic drugs. This guidance proposes that sponsors and applicants of PET drug products may request a waiver from complying with eCTD submission requirements if they meet certain factors set forth in the revised eCTD guidance. Although FDA proposes waiving eCTD requirements for these submissions, FDA continues to recommend use of the eCTD format for PET drug products if feasible. The Agency is issuing this revision to its guidance to propose this waiver.

Certain Type II DMFs. Type II DMFs are submitted to the Agency to make quality information available for Agency evaluation of the quality of active pharmaceutical ingredients and drug products used in investigational studies. Many such studies are conducted by academic, non-commercial sponsors where there is no commercial objective to support these applications. In some cases, the Type II DMF submission may be submitted by the academic sponsor or by a second party. For these academic IND sponsors, compliance with eCTD submission requirements can represent a significant burden and may present an obstacle to the conduct of research. After consideration of this regulatory burden and the potential negative impact on research and innovation, FDA proposes to waive the requirement to comply with eCTD submission requirements for certain Type II DMF submissions from an academic institution, government (State or Federal), or a non-profit research organization that are solely supporting a noncommercial application.

Short-Term Waivers. This guidance also describes the circumstances in which FDA proposes granting a temporary waiver from complying with eCTD submission requirements and the procedures for submitting requests for waivers.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7).''

FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance because this guidance contains binding provisions. In section 745A(a) of the FD&C Act (21 U.S.C. 379k–1), Congress granted explicit authorization to FDA to specify in guidance the format for the electronic submissions required under that section and required that FDA ''shall'' issue such guidance. Accordingly, this guidance explains such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words *must* or *required,* and therefore is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See *e.g.,* 21 CFR 10.115(d).

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014, 0910–0001, 0910–0338, and 0910–0308.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov*.

Dated: July 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15103 Filed 7–15–19; 8:45 am]

BILLING CODE 4164–01–P

[1] *https://www.federalregister.gov/documents/2000/03/10/00-5865/positron-emission-tomography-drug-products-safety-and-effectiveness-of-certain-pet-drugs-for.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–0372]

Determination That MIOCHOL (Acetylcholine Chloride Intraocular Solution), 20 Milligrams/Vial, 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, Agency, or we) has determined that MIOCHOL (acetylcholine chloride intraocular solution), 20 milligrams (mg)/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for acetylcholine chloride intraocular solution, 20 mg/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Meadow Platt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 301–796–1830.

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 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.

MIOCHOL (acetylcholine chloride intraocular solution), 20 mg/vial, is the subject of NDA 016211, held by Novartis Pharmaceutical Corporation (Novartis). MIOCHOL is indicated to obtain complete miosis of the iris in seconds after delivery of the lens in cataract surgery, in penetrating keratoplasty, iridectomy, and other anterior segment surgery where rapid, complete miosis may be required.

In a letter dated January 18, 2006, Novartis requested withdrawal of NDA 016211 for MIOCHOL (acetylcholine chloride intraocular solution). In the **Federal Register** of July 12, 2018 (83 FR 32305), FDA announced that it was withdrawing approval of NDA 016211, effective August 13, 2018.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated January 23, 2019, under 21 CFR 10.30, requesting that the Agency determine whether MIOCHOL (acetylcholine chloride intraocular solution), 20 mg/vial, 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 MIOCHOL (acetylcholine chloride intraocular solution), 20 mg/vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MIOCHOL (acetylcholine chloride intraocular solution), 20 mg/vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MIOCHOL (acetylcholine chloride intraocular solution), 20 mg/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MIOCHOL (acetylcholine chloride intraocular solution), 20 mg/vial, 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 MIOCHOL (acetylcholine chloride intraocular solution), 20 mg/vial, may 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.

Dated: July 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15089 Filed 7–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0117]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

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 information collection associated with the FDA ''Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims,'' which is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension.

DATES: Submit either electronic or written comments on the collection of information by September 16, 2019.

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 September 16, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 16, 2019. 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: