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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, is the subject of NDA 12–122 held by Eli Lilly, and initially approved onNovember 14, 1960. GLUCAGON is indicated for treatment of severe hypoglycemia and as a diagnostic aid in the radiologic examination of the stomach, duodenum, small bowel, and colon.

Under NDA 12–122, GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, was produced from animal sources. On September 11, 1998, FDA approved Eli Lilly's NDA 20–928 for GLUCAGON (glucagon rDNA origin), 1mg/vial. Subsequently, Eli Lilly discontinued sales of animal-sourced GLUCAGON in 2002. In 2005, FDA moved animal-sourced GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, to the ''Discontinued Drug Product List'' section of the Orange Book.

Walter G. Jump, on behalf of Cornerstone Regulatory, submitted a citizen petition dated August 7, 2007 (Docket No. FDA–2007–P–0248), under 21 CFR 10.30, requesting that the Agency determine whether animal-sourced GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition, reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal from sale of GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/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 GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. However, it is the Agency's view that it would be challenging for a prospective applicant to provide adequate data to meet the statutory requirements for an ANDA that relies on NDA 12–122 for GLUCAGON (glucagon hydrochloride) for injection in the absence of comparative data with the animal-sourced glucagon approved in NDA 12–122.

Dated: September 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22673 Filed 9–8–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1039]

Nonclinical Evaluation of Endocrine-Related Drug Toxicity; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Nonclinical Evaluation of Endocrine-Related Drug Toxicity.'' The purpose of this guidance is to clarify when additional studies are warranted after the standard toxicology tests have been conducted and there is a signal for potential adverse endocrine-related toxicity. This guidance finalizes the draft guidance entitled ''Endocrine Disruption Potential of Drugs: Nonclinical Evaluation'' issued on September 20, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT: Abby Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 22, Rm. 6474, Silver Spring, MD 20993–0002, 301–796–0174.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonclinical Evaluation of Endocrine-Related Drug Toxicity.'' This guidance focuses on nonclinical testing designed to assess the potential for a drug to cause endocrine effects that are

unintentional and adverse. The standard comprehensive test battery is generally sufficient to identify endocrine-related toxicity. Depending on the outcome of a standard battery of nonclinical tests, additional nonclinical studies may be warranted to more fully characterize the endocrine-related toxicity potential of a drug.

This guidance finalizes the draft guidance entitled ''Endocrine Disruption Potential of Drugs: Nonclinical Evaluation'' issued on September 20, 2013 (78 FR 57859). Revisions to the draft guidance address public comments and try to give more clarity regarding when additional studies could be appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on nonclinical evaluation of endocrine-related drug toxicity. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The 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 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

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 either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22683 Filed 9–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0221]

Formal Dispute Resolution: Appeals Above the Division Level; Revised Draft Guidance for Industry and Review Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry and review staff entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' This guidance is intended to provide recommendations for industry and review staff on the procedures in the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) for resolving scientific and/or medical disputes that cannot be resolved at the division level. This guidance describes procedures for formally appealing such disputes to the office or center level and providing information to assist FDA officials in resolving the issue(s) presented. This draft guidance revises the draft guidance of the same name issued March 13, 2013.

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 comment on this revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 8, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or 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 on the revised draft guidance 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.

FOR FURTHER INFORMATION CONTACT: Khushboo Sharma, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6468, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry and review staff entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' In the course of the review of applications for user fee products, a wide variety of scientific and/or medical issues are discussed that are critical to a sponsor's drug product development program. Sometimes, a sponsor may disagree with the Agency on a matter, and a dispute arises. Because these disputes often involve complex scientific and/or medical matters, it is critical that there be procedures in place to help ensure open, prompt discussion of such disputes. The procedures and policies described in this guidance are intended to promote rapid resolution of scientific and/or medical disputes between sponsors and CDER or CBER.

This draft guidance revises the draft guidance of the same name issued March 13, 2013 (78 FR 15955). Based on the docket comments for the draft guidance as well as on its own initiative, FDA made the following changes. The scope of the guidance was expanded to include formal dispute resolution requests for human drug applications covered under the Biosimilar User Fee Act of 2012. Additionally, certain areas were revised to provide more clarity, such as when a matter is and is not appropriate for a formal dispute resolution request, and information to include in the supporting background information. Also, this guidance clarifies that CDER and CBER intend to manage formal requests for appeals of scientific and/or medical