administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) 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: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21227 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0630]

Determination That PENTETATE ZINC TRISODIUM (Zinc Trisodium Diethylenetriaminepentaacetate) Solution for Intravenous or Inhalation Administration, Equivalent to 1 Gram Base/5 Milliliters (Equivalent to 200 Milligrams Base/Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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) has determined that PENTETATE ZINC TRISODIUM (zinc trisodium diethylenetriaminepentaacetate (Zn-DTPA)) solution for intravenous or inhalation administration, equivalent to (EQ) 1 gram (g) base/5 milliliters (mL) (EQ 200 milligrams (mg) base per mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Alexis Reisin Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6356, Silver Spring, MD 20993–0002, 301–796–3977.

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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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.

PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) is the subject of NDA 21–751, held by Hameln Pharmaceuticals GmbH, and initially approved on August 11, 2004. PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) is indicated for treatment of individuals with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination.

In a letter dated June 24, 2010, Hameln Pharmaceuticals GmbH notified the FDA that PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Heyl Chemisch-pharmazeutische Fabrik GmbH & Co. KG submitted a citizen petition dated December 6, 2010 (Docket No. FDA–2010–P–0630), under 21 CFR 10.30, requesting that the Agency determine whether PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) 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 product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)), 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 PENTETATE ZINC TRISODIUM (Zn-DTPA) solution for intravenous or inhalation administration (EQ 1 g base/5 mL (EQ 200 mg base/mL)) may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If the 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: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21245 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0215]

Draft Guidance for Industry and Food and Drug Administration Staff on In Vitro Companion Diagnostic Devices; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 12, 2011, the comment period for the notice that appeared in the **Federal Register** of July 14, 2011 (76 FR 41506). In the notice, FDA requested comments on a draft guidance document entitled ''In Vitro Companion Diagnostic Devices.'' The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit either written or electronic comments by October 12, 2011.

ADDRESSES: Submit electronic comments on the 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. 1601, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Mansfield, Center for Devices and Radiologic Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5676, Silver Spring, MD 20993–0002, 301–796–4664; or

Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5102, Silver Spring, MD 20993–0002, 301–796–0017; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 14, 2011 (76 FR 41506), FDA published a notice announcing the availability of the draft guidance entitled ''In Vitro Companion Diagnostic Devices,'' and the opening of a public docket to receive comments on the draft guidance document. Interested persons were invited to submit comments by September 12, 2011. At this time the Agency is extending the comment period until October 12, 2011, to continue to receive public comments. Comments submitted to the docket will assist in identifying issues to be addressed in the finalized guidance document.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

Dated: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21226 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0586]

Draft Guidance for Industry on Standards for Clinical Trial Imaging Endpoints; 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 ''Standards for Clinical Trial Imaging Endpoints.'' The purpose of this draft guidance is to assist sponsors in the use of imaging endpoints in clinical trials of therapeutic drugs and biological products. The draft guidance describes standards sponsors can use to ensure that clinical trial imaging data are obtained in a manner that complies with a trial's protocol, maintains imaging data quality, and provides a verifiable record of the imaging process.

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 draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 18, 2011.

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, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the 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:

Rafel Dwaine Rieves, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2354, Silver Spring, MD 20993 –0002, 301–796–2050; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Standards for Clinical Trial Imaging Endpoints.'' This draft guidance is intended to assist sponsors in the standardization of imaging procedures when an important imaging endpoint is used in a clinical trial of a therapeutic drug or biological product, especially for an efficacy endpoint. As part of the reauthorization of the Prescription Drug User Fee Act (PDUFA 4), FDA committed to certain performance goals (see letters from the Secretary of Health and Human Services to the Chairman of