

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the current investigational new animal drug/new animal drug application reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: June 25, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-15792 Filed 7-1-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0032]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Labeling; Notification Procedures for Statements on Dietary Supplements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Labeling; Notification Procedures for Statements on Dietary Supplements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5733, [domini.bean@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On March 27, 2013, the Agency submitted a proposed collection of information entitled "Food Labeling; Notification Procedures for Statements on Dietary Supplements" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0331. The approval expires on May 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 26, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-15794 Filed 7-1-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-1106]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5733, [domini.bean@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On March 25, 2013, the Agency submitted a proposed collection of information entitled, "Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0509. The approval expires on May 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 26, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-0576]

#### Draft Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products" dated July 2013. The draft guidance document provides sponsors of Investigational New Drug Applications (INDs) for cellular therapy (CT) and gene therapy (GT) products (referred to collectively as CGT products) with recommendations to assist in designing early-phase clinical trials of CGT products.

**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 November 22, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), 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. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. 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:** Melissa Reisman, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a draft guidance document entitled "Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products," dated July 2013. The draft guidance document provides sponsors of INDs for CGT products with recommendations to assist in designing early-phase clinical trials of CGT products. The scope of this guidance is limited to products for which the Office of Cellular, Tissue and Gene Therapies/FDA has regulatory authority. CGT products within the scope of this guidance meet the definition of "biological product" in section 351(i) of the Public Health Service (PHS) Act (42 U.S.C. 262(i)). The guidance does not apply to those human cells, tissues, and cellular-and tissue-based products (HCT/PS) regulated solely under section 361 of the PHS Act (42 U.S.C. 264), to products regulated as medical devices under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), or to the therapeutic biological products for which the Center for Drug Evaluation and Research (CDER) has regulatory responsibility.

The design of early-phase clinical trials of CGT products often differs from the design of clinical trials for other types of pharmaceutical products. Differences in trial design are necessitated by the distinctive features of these products, and also may reflect previous clinical experience. The draft guidance document describes features of CGT products that influence clinical trial design, including product characteristics, manufacturing considerations and preclinical considerations, and suggests other documents for additional information. Consequently, the draft guidance document provides recommendations with respect to these products as to clinical trial design, including early-phase trial objectives, choosing a study population, using a control group and blinding, dose selection, treatment plans, monitoring and follow-up. Finally, the draft guidance encourages prospective sponsors to meet with FDA review staff regarding their IND submission and offers references for additional guidance on submitting an IND.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not

operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

**II. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 part 312 have been approved under OMB control number 0910–0014.

**III. Comments**

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 25, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA–2013–D–0744]

**Draft Guidance for Industry on Antibacterial Therapies for Patients With Unmet Medical Need for the Treatment of Serious Bacterial Diseases; 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 "Antibacterial Therapies for Patients With Unmet Medical Need for the Treatment of Serious Bacterial Diseases." The purpose of the draft guidance is to assist sponsors in the development of new antibacterial drugs to treat serious bacterial diseases, particularly in areas of unmet need, and new antibacterial drugs that are pathogen-focused (i.e., drugs that have a narrow spectrum of activity or are only active against a single genus or species of bacteria).

**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 September 30, 2013.

**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. 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 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:** Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Antibacterial Therapies for Patients With Unmet Medical Need for the Treatment of Serious Bacterial Diseases." The purpose of this draft guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of serious bacterial diseases in patients with unmet medical needs and new antibacterial drugs that are pathogen-focused (i.e., drugs that