

314.71, 314.97 and 601.12; and the content and format of prescription drug labeling submitted under 21 CFR 201.56 and 201.57. These collections of information are subject to review by OMB under the PRA act and are approved under OMB control numbers 0910-0001, 0910-0338, and 0910-0572. Section V of the draft guidance refers to the guidance entitled "Formal Dispute Resolution: Appeals Above the Division Level," which describes collections of information approved under OMB control number 0910-0430.

IV. Electronic Access

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

Dated: April 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1998-D-0281]

Guidance for Industry and Food and Drug Administration Staff; 30-Day Notices, 135-Day Premarket Approval Supplements and 75-Day Humanitarian Device Exemption Supplements for Manufacturing Method or Process Changes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes." This document provides guidance on the type of changes to an approved application that FDA believes may qualify for submission as 30-day notices, the type of information to submit in a 30-day notice, and the user fees associated with these submissions. The guidance document is immediately in effect, but it remains subject to comment in accordance with the

Agency's good guidance practices (GGP).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

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:

For devices regulated by CDRH: Anastacia Bilek, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3656, Silver Spring, MD 20993-0002, 301-796-5588.

For devices regulated by CBER: 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 guidance for industry entitled "30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes." This guidance is being issued consistent with FDA's GGP regulation (§ 10.115 (21 CFR 10.115)). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because statutory provisions regarding medical device user fees under the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85) are

in effect and being implemented, and guidance is needed to help effect such implementation. Although this guidance is immediately in effect, it remains subject to comment in accordance with the Agency's GGP regulation.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107-250) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. *et seq.*) to authorize FDA to collect user fees for the review of certain premarket submissions (See section 708 of the FD&C Act (21 U.S.C. 379j)). FDAAA further amended the FD&C Act to extend FDA's authority to collect medical device user fees through September 30, 2012, and added 30-day notices to the types of premarket submissions subject to user fees (21 U.S.C. 379j(a)(2)(A)(vi)). For additional information on the MDUFMA, please see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>.

This guidance supersedes the previous guidance document entitled "30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH," that published in the **Federal Register** of February 25, 1998 (63 FR 9570). This guidance describes the user fees authorized, updates the previous guidance to clarify the process for submitting a 30-day notice, and provides additional information on the types of changes that may be submitted. The previous guidance did not include information on HDEs even though certain modifications to a manufacturing procedure or method of manufacture for HDEs are subject to the 30-day notice provisions. The current guidance includes this information.

The guidance represents the Agency's current thinking on 30-day notices, 135-day PMA supplements and 75-Day HDE supplements for manufacturing method or process changes. 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 requirements of the applicable statute and regulations.

II. Paperwork Reduction Act of 1995

This 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 21 CFR part 814, subparts B and E, have been approved under OMB control number 0910-0231; the collections of information 21 CFR part 814, subpart H, have been approved under OMB control number 0910-0332; the collections of information 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in FDA form 3601 have been approved under OMB control number 0910-0511; and the collections of information in FDA form 3602a have been approved under OMB control number 0910-0508.

III. 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. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: April 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0044]

Guidance for Industry on Influenza: Developing Drugs for Treatment and/or Prophylaxis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Influenza: Developing Drugs for Treatment and/or Prophylaxis." This

guidance is intended to assist sponsors in the clinical development of drugs and therapeutic biological products for the treatment and/or prophylaxis of illness caused by influenza viruses A and B, including both seasonal and pandemic varieties. This guidance finalizes the draft guidance issued February 20, 2009.

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, 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 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:

Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6360, Silver Spring, MD 20993-0002, 301-796-1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Influenza: Development of Drugs for Treatment and/or Prophylaxis." Because of the public health implications of both epidemic and pandemic influenza, the variable nature of the disease, the limited therapeutic options, and challenges in studying new options, FDA is issuing guidance to assist sponsors in all phases of influenza drug development.

This guidance addresses nonclinical development, early phases of clinical development, phase 3 protocol designs and endpoints for the treatment of both uncomplicated and serious influenza, and protocol designs for prevention of symptomatic influenza. Other issues that are addressed in this guidance include the role of animal data in an influenza drug development program, and considerations relating to the potential for emergency access to influenza drugs, including advance development of protocols for further exploration and verification of drug

effects under epidemic and pandemic conditions.

A draft notice of availability of this guidance was published for comment in the **Federal Register** of February 20, 2009 (74 FR 7908). Comments we received on the draft guidance have been considered and the guidance has been revised as follows: (1) Clarification on the size of a safety database needed to support filing of a new drug application for the treatment of serious influenza; (2) elaboration on why virologic endpoints are not currently acceptable primary efficacy endpoints in phase 3 studies; (3) a recommendation for the inclusion of sensitive and specific assays (*e.g.*, real-time polymerase chain reaction assay) for laboratory confirmation of influenza infection to assist in defining the infected population for analyses in influenza treatment trials; and (4) additional statements regarding proposals for potential emergency use authorizations of antiviral drugs for influenza.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on developing drugs for treatment and/or prophylaxis of influenza illness. 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 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 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. It is no longer necessary to send two copies of mailed 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.