4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0164]

Guidance for Industry: Safety Labeling Changes--Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act; 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 "Safety Labeling Changes--Implementation of Section 505(o)(4) of the FD&C Act." The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizing FDA to require certain drug and biological product application holders to make safety-related labeling changes based upon new safety information that becomes available after the drug or biological product is approved under the FD&C Act or the Public Health Service Act (the PHS Act). This final guidance provides information on the implementation of section 505(o)(4) of the FD&C Act, including a description of the types of safety labeling changes that ordinarily might be required under this section; how FDA plans to determine what constitutes new safety information; the procedures involved in requiring safety labeling changes; and enforcement of the requirements for safety labeling changes.

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; or 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. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. 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: Kristen Everett, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6484, Silver Spring, MD 20993-0002, 301-796-0453; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Safety Labeling Changes--Implementation of Section 505(o)(4) of the FD&C Act." In the past, FDA has requested that holders of applications for approved products make labeling changes related to safety after approval to address serious risks. In most cases, application holders responded to these requests by negotiating appropriate language with FDA staff to address the concerns and then submitting a supplement or amended supplement to obtain approval of the change.

However, negotiations were often protracted, and FDA had few tools available at its disposal to end negotiations and require the changes. Congress recognized the limitations of FDA's authority in this area and, in FDAAA, gave FDA new authorities to require safety labeling changes in certain circumstances.

Title IX, section 901 of FDAAA (Public Law 110-85) amended the FD&C Act by adding new section 505(o)(4) (21 U.S.C. 355(o)(4)). Section 505(o)(4) authorizes FDA to require, and if necessary, order labeling changes if FDA becomes aware of new safety information that FDA believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the PHS Act (42 U.S.C. 262). Specifically, section 505(o)(4) of the FD&C Act applies to prescription drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application (BLA) under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act if the NDA reference listed drug is not currently marketed. The safety labeling changes provisions in section 505(o)(4) apply to the previously listed products, including products that are not marketed, unless approval of the NDA, BLA, or ANDA has been withdrawn in the Federal Register. FDAAA imposes timeframes for application holders to submit and FDA staff to review safety labeling changes, and gives FDA new enforcement tools to bring about timely and appropriate labeling changes.

In the Federal Register of April 13, 2011 (76 FR 20686), FDA announced the availability of a draft guidance for industry entitled "Safety Labeling Changes--Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act." The notice gave interested parties the opportunity to comment by July 12, 2011. FDA carefully considered all of the comments

received, and revised the guidance as appropriate. This guidance is intended to clarify how FDA will implement section 505(o)(4) of the FD&C Act, including providing a description of the types of safety labeling changes that ordinarily might be required under this section; how FDA plans to determine what constitutes new safety information; what procedures are involved in requiring safety labeling changes; and how FDA will enforce the requirements for safety labeling changes.

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 implementation of section 505(o)(4) of the FD&C Act. 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. 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.

III. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information have been approved under OMB control number 0910-0734. This guidance also refers to previously approved collections of information.

Specifically, the guidance describes: Labeling supplements for NDAs, ANDAs, and BLAs submitted under 21 CFR 314.70, 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 and are approved under OMB control numbers 0910-0001, 0910-0338, and 0910-0572. Section V of the 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 either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: July 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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