

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0303]

Draft Guidance for Industry on Public Availability of Labeling Changes in “Changes Being Effectuated” Supplements; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Public Availability of Labeling Changes in ‘Changes Being Effectuated’ Supplements.” The guidance announces to holders of a new drug application (NDA), an abbreviated new drug application (ANDA), or a biologics license application (BLA), who intend to submit a “Changes Being Effectuated” supplement (CBE supplement) to make a postapproval labeling change, that FDA will make labeling revisions identified in a CBE supplement publicly available upon receipt of the supplement by FDA. The guidance does not have any bearing on supplements that relate to chemistry, manufacturing, and controls changes, nor does it expand the circumstances in which an ANDA holder may effect labeling changes via a CBE supplement.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the **Federal Register***]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and

Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Meredith S. Francis, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Public Availability of Labeling Changes in ‘Changes Being Effected’ Supplements.” FDA has begun an initiative to facilitate computerized access to drug information by consumers, pharmacists, and health care providers so that they will have faster and more comprehensive access to drug information. As part of this initiative, the agency has been involved in the development of a computerized repository of a broad array of drug information, known as “DailyMed.” Among other things, DailyMed contains the information referred to as “content of labeling,” which includes all the information found in prescription drug labeling and over-the-counter (OTC) drug facts labeling, including all text, tables, and figures (see 21 CFR 314.50(l)(1)(i)). To maximize its ability to serve as a useful resource to consumers, pharmacists, and health care providers, DailyMed must contain the most up-to-date and comprehensive drug information available.

Sections 314.70 and 601.12 (21 CFR 314.70 and 601.12) of FDA regulations identify the types of supplemental applications that must be submitted to FDA to effect a labeling change to approved NDAs, ANDAs, and BLAs. Certain types of changes to labeling should receive FDA approval before the changes are implemented. These include all labeling changes that do not fall under § 314.70(c)(6)(iii), (d)(2)(ix), or (d)(2)(x), or under § 601.12(f)(2) or (f)(3). Other changes may be implemented by a sponsor upon the agency's receipt of a CBE supplement. These changes are identified in §§ 314.70(c)(6)(iii) and 601.12(f)(2)(i).

In the past, FDA has not made labeling publicly available until it has been approved, either under a pre-approval supplement or under a CBE supplement. To make the most current labeling submitted to FDA available to health care practitioners and the public, and to facilitate the DailyMed initiative, FDA will make the revised labeling proposed in a CBE supplement publicly available on its Web site and through DailyMed shortly after the CBE supplement is received and before FDA has necessarily reviewed or approved it. If, after reviewing the CBE supplement, FDA decides it should not be approved, FDA will either: (1) Remove the labeling submitted with the CBE supplement from FDA's Web site and from DailyMed and replace that labeling with the previous labeling; or (2) recommend the sponsor amend its labeling and, after the sponsor submits the amended labeling, post the amended labeling on FDA's Web site and provide it to DailyMed promptly.

A sponsor should not submit a CBE supplement to FDA until the sponsor is ready to distribute the labeling that it proposes in that CBE supplement. FDA will consider the submission of a CBE supplement to be consent by the sponsor to post the proposed labeling on FDA's Web site and on DailyMed.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on public availability of labeling changes in CBE supplements. 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 to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: September 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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