will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs for the products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: February 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–4469 Filed 3–6–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0142]

Draft Guidance for Industry and Review Staff on Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and review staff entitled ''Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route.'' The draft guidance provides recommendations concerning development of safety profiles to support approval of reformulated drug products and products proposed for use by a route of administration for which the product was not previously approved.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 6, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul Brown, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5172, Silver Spring, MD 20993–0002, 301–796–0856.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled ''Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route.'' This draft guidance is intended for individuals or organizations and review staff in the Center for Drug Evaluation and Research involved in the development and review of new formulations of products containing previously approved drug substances and proposals for existing formulations to be used in a new route of administration. This draft guidance assumes that the drug substance has already been used in an approved drug product. It outlines the nonclinical information generally recommended to support the development of a new formulation containing a previously approved drug substance.

This draft guidance also provides nonclinical evaluation information for formulations intended for use by new routes of administration even if there is no change in the composition of the formulation. Although this situation does not represent a reformulation, it is appropriate in this case to reevaluate the toxicity information using considerations outlined in the draft guidance.

This draft guidance does not absolve the sponsor from providing complete nonclinical information for a drug product, either directly or through a right of reference to such information or by relying on the finding of safety and effectiveness for a listed drug and establishing a clinical bridge to that listed drug. This draft guidance pertains to new formulations containing previously approved drug substances only and does not address the safety evaluation of excipients.

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 the safety evaluation of reformulated drug products, including products intended for administration by an alternate route. 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 regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

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: February 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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