

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D-1392]

DDM

Display Date 6-8-04  
Publication Date 6-9-04  
Certifier R. W. DESMA

**Guidance for Industry on Botanical Drug Products; Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Botanical Drug Products." FDA has revised a draft guidance issued on August 11, 2000, in response to comments from industry and other interested persons. The guidance explains the circumstances under which FDA regulations require approval of a new drug application (NDA) for marketing of a botanical drug product and when such a product may be marketed under an over-the-counter (OTC) drug monograph. It also provides guidance to sponsors on submitting investigational new drug applications (INDs) for botanical drug products.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this 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 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Shaw T. Chen, Center for Drug Evaluation and Research (HFD-105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2601.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of August 11, 2000 (65 FR 49247), FDA published a notice announcing the availability of a draft guidance for industry entitled “Botanical Drug Products.” In a notice published in the **Federal Register** of December 15, 2000 (65 FR 78496), FDA reopened the comment period on the draft guidance until March 15, 2001.

FDA received a number of comments on the botanical drugs draft guidance. FDA has made a few substantive changes along with several editorial revisions to the draft guidance. For example, FDA has revised the guidance to emphasize the importance of maintaining batch-to-batch consistency in the drug substance and drug product used throughout the clinical development process. FDA also is adding to the final guidance a section that provides answers to what the agency expects may be frequently asked questions concerning the guidance.

**II. Description of the Guidance**

The guidance is intended to encourage the clinical study and submission for marketing approval of botanical drug products. The guidance explains the circumstances under which FDA regulations require approval of an NDA submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) before marketing a botanical drug and when such a drug

may be marketed under an OTC drug monograph. The guidance also provides scientific and regulatory guidance to sponsors about conducting initial and expanded clinical investigations of botanical drugs, including those botanical products currently lawfully marketed as foods and dietary supplements in the United States.

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 the development of botanical drug products. 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.

### **III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### **IV. The Paperwork Reduction Act of 1995**

This guidance contains no new information collection provisions 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 guidance explains the circumstances under which FDA regulations require approval of an NDA for marketing a botanical drug product and when such a product may be marketed under an OTC drug monograph. The regulations governing the preparation and submission of an NDA are in part 314 (21 CFR part 314), and

the guidance does not contain any recommendations that exceed the requirements of these regulations. FDA estimated the information collection requirements resulting from the preparation and submission of an NDA, and OMB approved the reporting and recordkeeping burden until March 31, 2005, under OMB control number 0910–0001. FDA anticipates that any NDAs submitted for botanical drug products would be included under the burden estimates approved by OMB for part 314.

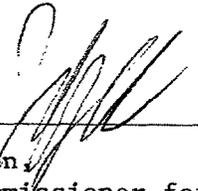
The regulations on the procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing OTC drug monographs, are set forth in § 330.10 (21 CFR 330.10). FDA believes that any botanical drug products that may be eligible for inclusion in an OTC drug monograph under current § 330.10 have already been or presently are being considered for such inclusion.

The guidance also provides scientific and regulatory guidance to sponsors on conducting clinical investigations of botanical drugs. The regulations governing the preparation and submission of INDs are in part 312 (21 CFR part 312). The guidance does not contain any recommendations that exceed the requirements in those regulations. FDA estimated the information collection requirements resulting from the preparation and submission of an IND under part 312, and OMB approved the reporting and recordkeeping burden until January 31, 2006, under OMB control number 0910–0014.

## **V. Electronic Access**

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

Dated: 6/2/04  
June 2, 2004.



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[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

