

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date	8-10-00
Publication Date	8-11-00
Certifier	SN Reese

[Docket No. 00D-1392]

Draft Guidance for Industry on Botanical Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Botanical Drug Products." This draft guidance explains the circumstances under which FDA approval of a new drug application (NDA) is required for marketing of a botanical drug product and when such a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 researchers and manufacturers on conducting initial and expanded clinical investigations of botanical drug products. After evaluating the comments it receives, FDA will issue this guidance in final form to encourage the submission of investigational new drug applications (IND's) for botanical drugs.

DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].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ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug

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Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Yuan-yuan Chiu, Center for Drug Evaluation and Research (HFD-800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5918.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

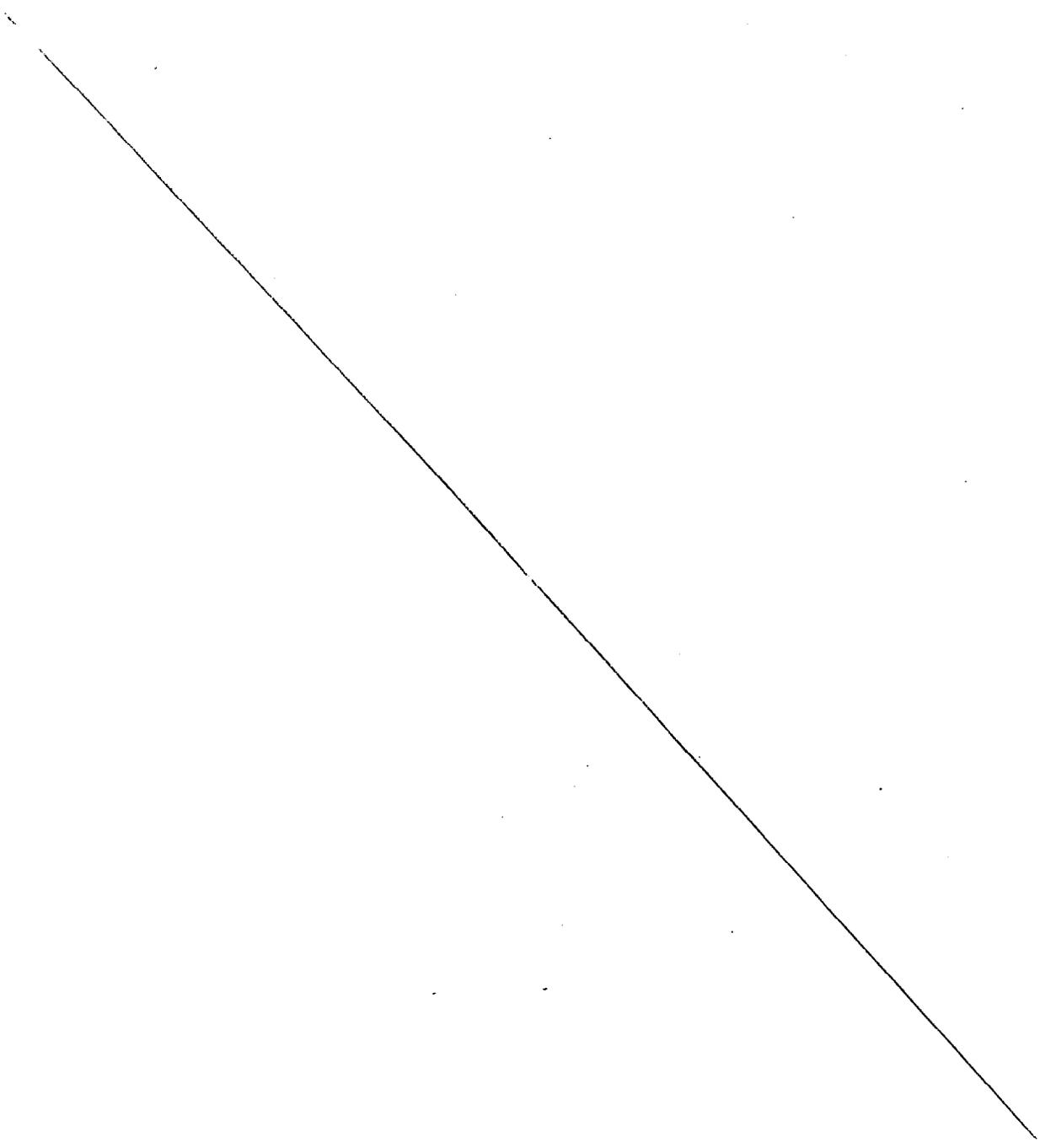
FDA is announcing the availability of a draft guidance for industry entitled “Botanical Drug Products.” Botanical products are finished, labeled products that contain vegetable matter, which may include plant material, algae, macroscopic fungi, or combinations of these substances. Botanical products may be intended for use as drugs, foods (including dietary supplements), or cosmetics.

This 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 approval of an NDA is required for marketing a botanical drug and when such a drug may be marketed under an OTC drug monograph. The draft 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. In particular, the guidance provides information on how the agency will interpret and apply to botanical drugs certain provisions of existing regulations on the submission of IND’s (21 CFR part 312).

This level 1 draft guidance is being issued in accordance with FDA’s good guidance practices (62 FR 8961, February 27, 1997). The draft 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, regulations, or both.

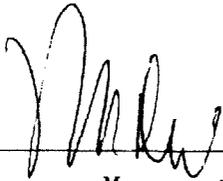
II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by [*insert date 60 days after date of publication in the **Federal Register***]. Two copies of any 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 draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/31/00
July 31, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

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COPY OF THE ORIGINAL**
Suzette N. Reese