

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1392]

*DMB*

Display Date	<i>12-14-00</i>
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Certifier	<i>SKOOR</i>

**Draft Guidance for Industry on Botanical Drug Products; Availability; Reopening of Comment Period**

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

**ACTION:** Notice; reopening of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for the draft guidance for industry entitled “Botanical Drug Products” until [*insert date 90 days after date of publication in the Federal Register*]. This draft guidance explains the circumstances under which FDA approval of a new drug application (NDA) is required for marketing of a botanical drug product and when such a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. FDA is taking this action in response to a request for an extension.

**DATES:** Submit written comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*].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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5918. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration,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.

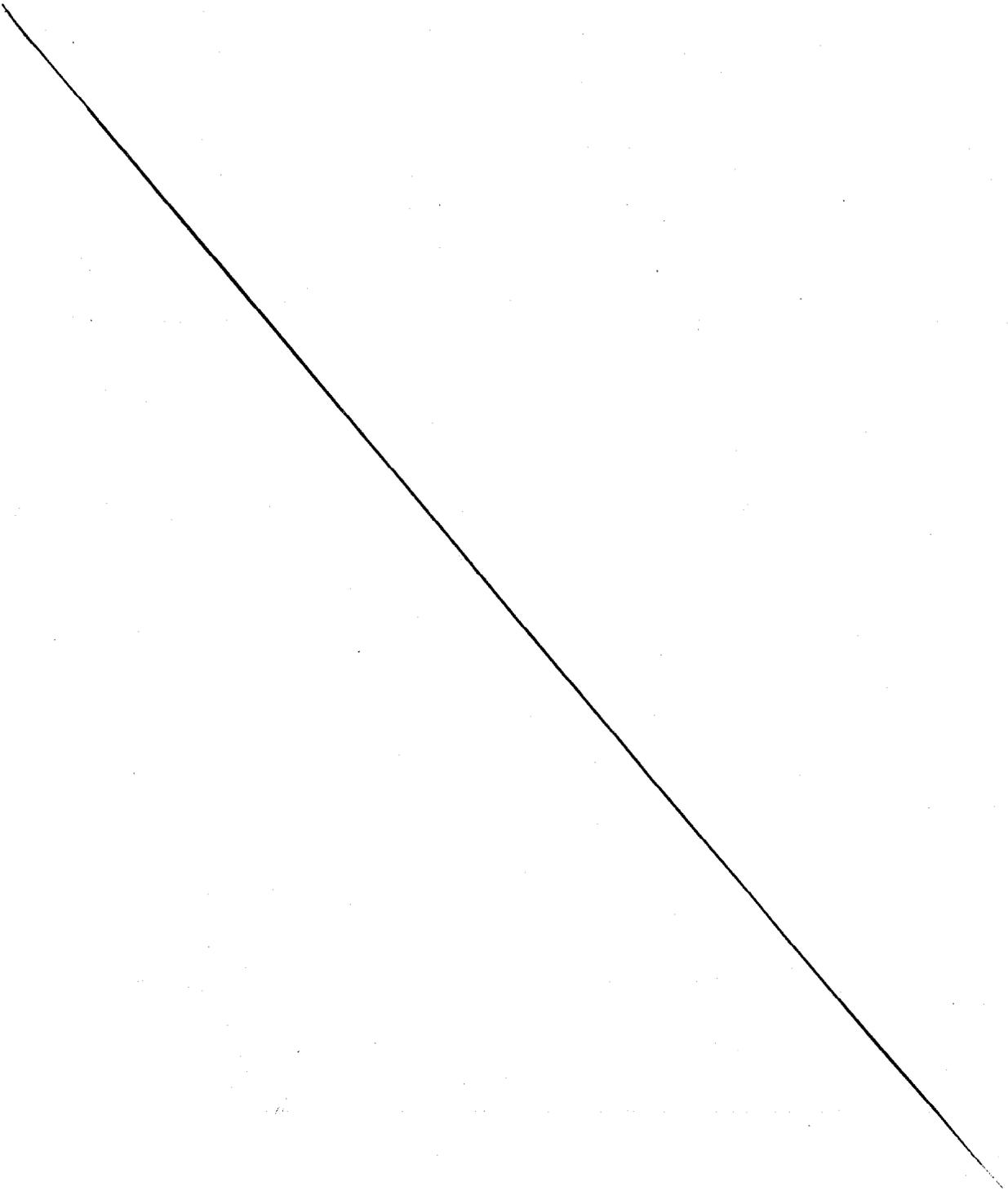
**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 11, 2000 (65 FR 49247), FDA published a notice announcing the availability of a draft guidance for industry entitled "Botanical Drug Products." The draft guidance is intended to encourage the clinical study and submission for marketing 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 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. 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 investigational new drug applications (IND's) (21 CFR part 312). Interested persons were given until October 10, 2000, to submit written comments on the draft guidance.

FDA received a letter, dated September 15, 2000, from Diane C. McEnroe of the firm of Sidley & Austin, in behalf of a research-based company based in Asia, requesting that the agency extend the comment period on the draft guidance by 90 days.

The draft guidance introduces several new and highly technical issues. Therefore, the agency has decided to reopen the comment period on the draft guidance until [*insert date 90 days after date of publication in the Federal Register*], to allow the public more time to review and comment on its contents.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document by [*insert date 90 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 12/7/00  
December 7, 2000



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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

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