

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01 D-05821

DMB

Display Date	02-06-02
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Certifier	A. Corbin

**Draft Guidance for Industry on Available Therapy; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Available Therapy." The document is intended to provide guidance to industry on the meaning of the term available therapy, as used by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

**DATES:** Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the **Federal Register]***.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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:** For information regarding human drug products: Janet Jones, Center for Drug Evaluation and Research (HFD-040), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5445.

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For information regarding biological products: Karen Weiss, Center for **Biologics** Evaluation and Research (**HFM-570**), Food and Drug Administration; 1401 Rockville Pike, Rockville, MD 20852-1148, 301-827-5093.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Available Therapy.” Available therapy and related terms, such as existing treatments and existing therapy, appear in a number of regulations and policy statements issued by CDER and CBER, but these terms have never been formally defined by the agency. Some confusion has arisen regarding whether available therapy refers only to products approved by FDA for the use in question, or whether it could also refer to products used off-label or to treatments not regulated by FDA, such as surgery. The draft guidance document is intended to inform the public of the agency’s interpretation of available therapy.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). It represents the agency’s current thinking on this topic. 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**

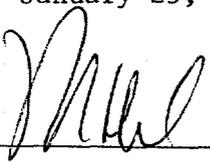
Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the 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.

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### III. Electronic Access

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

Dated: 1/25/02  
January 25, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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