

DDM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 7-22-04
Publication Date 7-23-04
Certifier A. Corbin

[Docket No. 2001D-0582]

Guidance for Industry on Available Therapy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a 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 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:

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.

For information regarding biological products: Robert Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1148, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Available Therapy.” The term “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 about, for example, whether “available therapy” refers only to products approved by FDA for the use in question, or whether the term could also refer to products used off-label or to treatments not regulated by FDA, such as surgery. The guidance document is intended to inform the public of the agency’s interpretation of the term “available therapy.”

In the **Federal Register** of February 7, 2002 (67 FR 5831), FDA announced the availability of a draft guidance entitled “Available Therapy.” The document provided interested persons an opportunity to submit comments by April 8, 2002. On October 17, 2002, the United States District Court for the District of Columbia invalidated the “Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients” (the pediatric rule) and enjoined FDA from enforcing the

rule. (See *Association of Am. Physicians and Surgeons, Inc. v. United States Food and Drug Admin.*, 2002 U.S. Dist. LEXIS 19689 (Oct. 17, 2002).) As a result, FDA has deleted all references to the pediatric rule in the guidance.

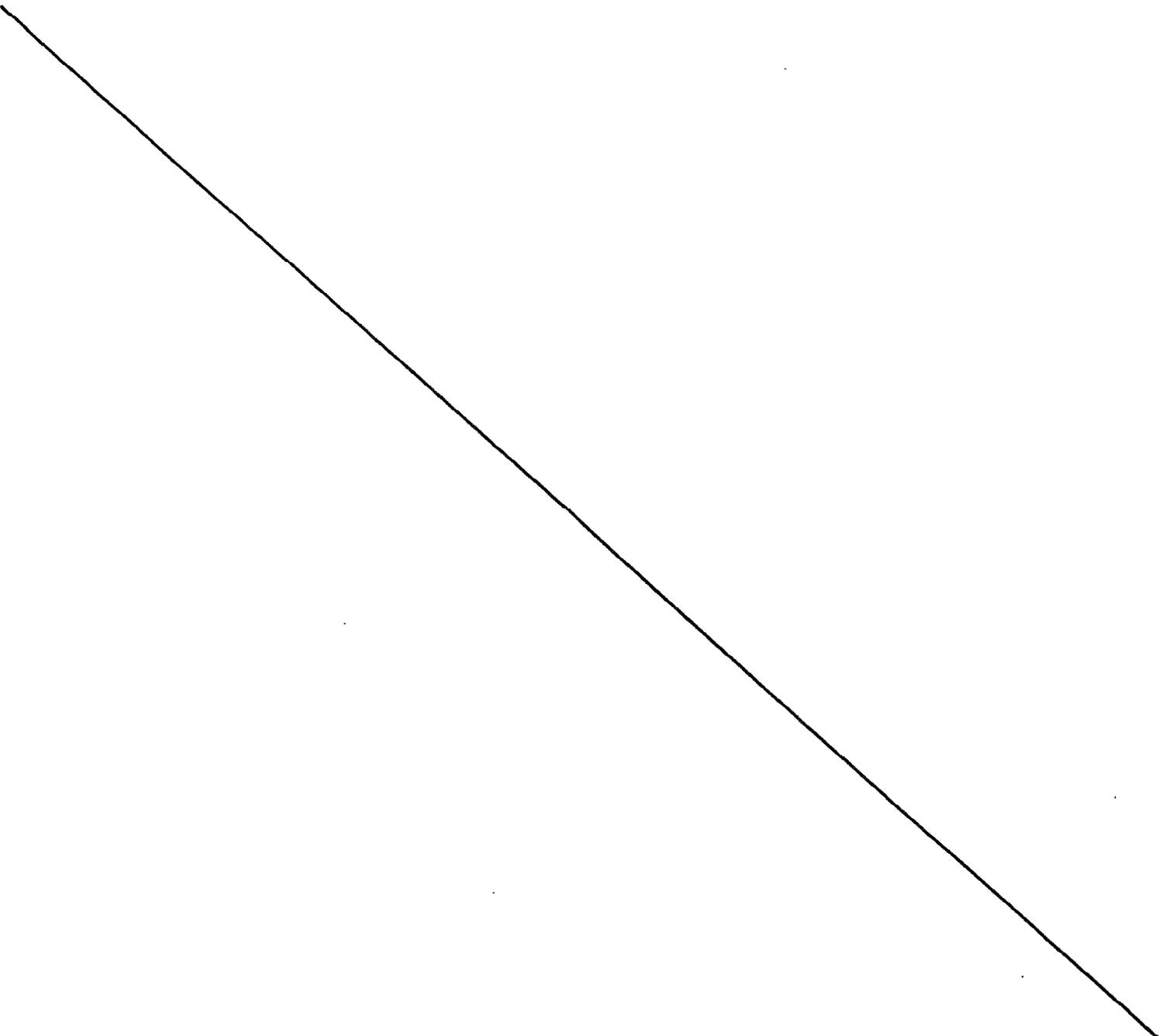
In addition, FDA has revised the definition of “available therapy.” The revised definition seeks to resolve issues raised in comments requesting clarification of the proposed definition and confusion about situations where the only available therapy has been approved under the accelerated approval regulations (21 CFR 314.500 and 601.40). The term “available therapy” has been revised to explain that the existence of a therapy already approved under the accelerated approval regulations will not necessarily preclude additional therapies for the same specific indication from being approved under the accelerated approval regulations or designated for the Fast Track drug development programs.

The revisions to the definition of “available therapy” affect FDA’s Fast Track drug development programs. As a result, FDA has similarly revised its guidance for industry on Fast Track Drug Development Programs—Designation, Development and Application Review to discuss situations where the only available therapy is approved under the accelerated approval regulations.

This Level 1 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

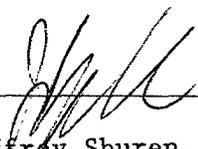
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets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



III. Electronic Access

Persons with access to the Internet may obtain the document at either <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: 7/16/04
July 16, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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

BILLING CODE 4160-01-S

