

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier R. LEDESMA

[Docket No. 02D-0094]

Draft Guidance for Industry on IND Exemptions for Studies of Lawfully Marketed Cancer Drug or Biological Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "IND Exemptions for Studies of Lawfully Marketed Cancer Drug or Biological Products." This guidance clarifies FDA's policy on exemption from investigational new drug (IND) application requirements for studies of marketed cancer drug or biological products. This guidance is intended to decrease the burden to investigators and regulators of submitting unnecessary IND applications.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].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ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, <http://www.fda.gov/cder/guidance/index.htm>, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, <http://www.fda.gov/cber/guidelines.htm>. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800,

or by calling the Fax Information System at 1-888-CBER-FAX or 301-827-3844. Submit written or electronic comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Grant A. Williams, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5740, or Patricia Keegan, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5093.

SUPPLEMENTARY INFORMATION:

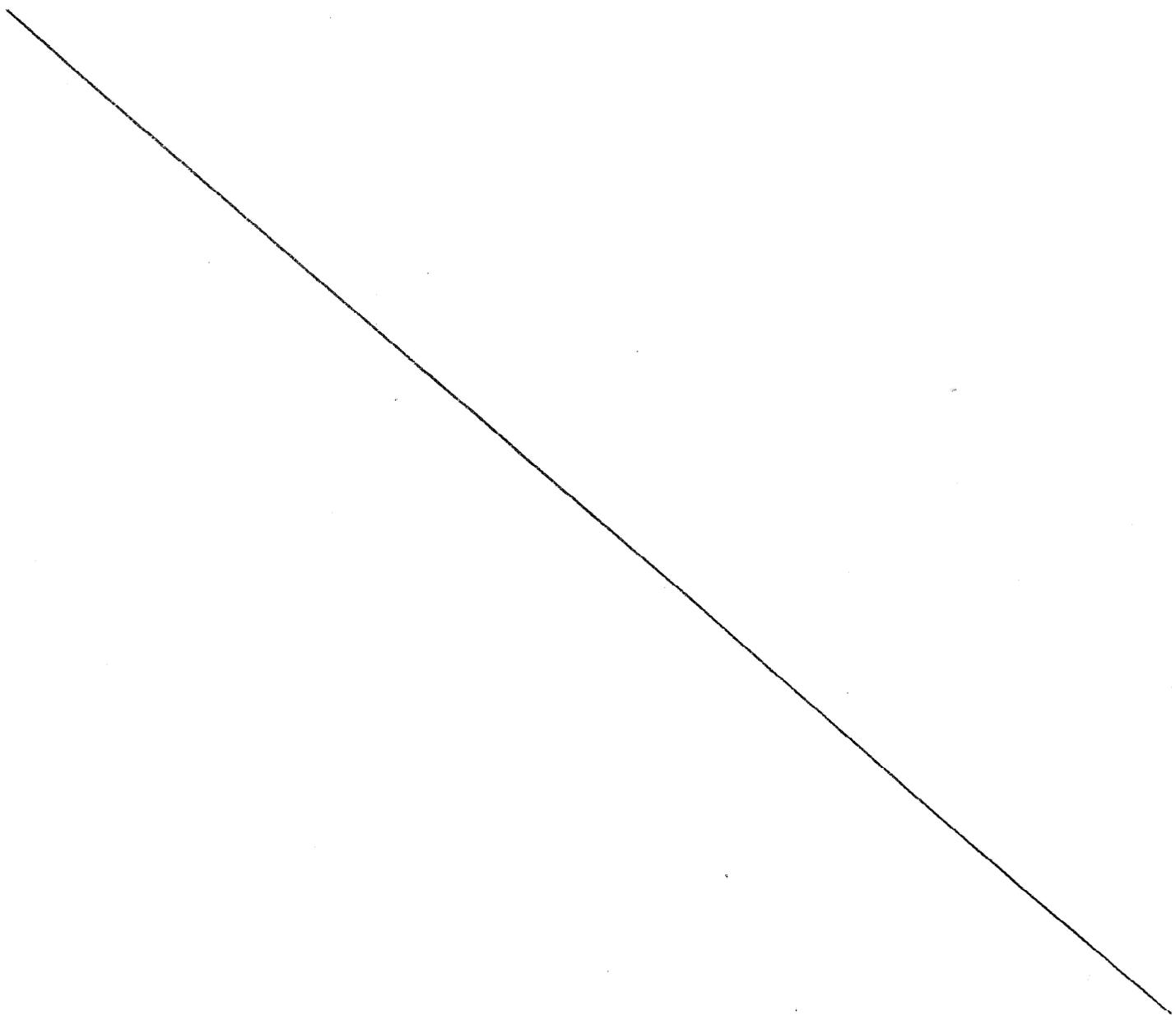
I. Background

FDA is announcing the availability of a draft guidance for industry entitled “IND Exemptions for Studies of Lawfully Marketed Cancer Drug or Biological Drug Products.” Exemption of certain studies of marketed drugs from IND regulation is allowed under 21 CFR 312.2(b)(1). Investigations that involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product are not exempt. This guidance discusses the risk/benefit determination in the practice of oncology, the pertinent regulations relating to exemption of INDs, FDA’s policy for determining exemption status, and specific examples of studies generally considered exempt.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on IND exemptions for studies of lawfully marketed cancer drug or biological 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.

II. Comments

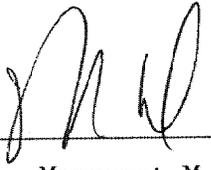
Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the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



III. Electronic Access

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

Dated: 3/29/02
March 29, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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

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