PDM

Display Date 5-15-07
Publication Date 5-16-07
Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0112]

Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics; 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 "Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics." This guidance provides recommendations to applicants on endpoints for cancer clinical trials submitted to FDA to support effectiveness claims in new drug applications, biologics license applications, or supplemental applications. Applicants are encouraged to use this guidance to design cancer clinical trials and to discuss protocols with the agency. This guidance provides background information and discusses general regulatory principles. Additional companion guidances will follow and will focus on endpoints for specific cancer types (e.g., lung cancer, colon cancer) to support drug approval or labeling claims. This guidance, and the subsequent indication-specific guidances, should speed the development and improve the quality of protocols submitted to the agency to support anticancer effectiveness claims.

DATES: Submit written or electronic comments on agency guidances at any time.

Cd06138 2005D-0112 NAD 2

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, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. 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:

Rajeshwari Sridhara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1210, Silver Spring, MD 20903–0002, 301–796–2070; or

Peter Bross, Center for Biologics Evaluation and Research (HFM–755), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics." FDA is developing guidance on oncology endpoints through a process that

includes public workshops of oncology experts and discussions before FDA's Oncologic Drugs Advisory Committee. This guidance provides background information and general principles. The endpoints discussed in this guidance are for drugs to treat patients with an existing cancer. This guidance does not address endpoints for drugs to prevent or decrease the incidence of cancer.

The availability of a draft of this guidance was announced in the **Federal Register** of April 4, 2005 (70 FR 17095). Comments received from industry, professional societies, and consumer groups on the draft guidance have been taken into consideration by FDA in finalizing this guidance, and some of the changes are summarized here. The section on future methods for assessing progression has been clarified based on the comments received and FDA's current thinking and practice. The section on no treatment or placebo control and the section on isolating drug effect in combination also have been clarified based on the comments received and FDA's view that these do not directly concern the selection or evaluation of endpoints. Throughout the guidance document, the language has been condensed and simplified to be concise and clear.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on clinical trial endpoints for the approval of cancer drugs and biologics. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under 0910–0014; the collections of information in 21 CFR part 314 have been approved under 0910–0001, and the collections of information referred to in the guidance for industry entitled "Special Protocol Assessment" have been approved under 0910–0470.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

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

Dated: May 10, 2007. 5/10/07

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07–????? Filed ??–??–07; 8:45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Dawn P. Harkins