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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 99D-0484]

Draft Guidance for Industry on Accelerated Approval Products: Submission of Promotional Materials; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Accelerated Approval Products: Submission of Promotional Materials." The accelerated approval regulations require that applicants, unless otherwise informed by the agency, submit to FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling and advertisements, intended for dissemination or publication within 120 days following marketing approval. This draft guidance is intended to assist sponsors of drug and biological products who are submitting such materials as part of the accelerated approval process.

DATES: Written comments on the draft guidance may be submitted by (*insert date 60 days after date of publication in the Federal Register*).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ADDRESSES: Copies of this draft guidance are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>", or "<http://www.fda.gov/cber/guidelines.htm>". Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD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 Submit written comments on the draft guidance to the Dockets Management Branch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, or FAX 301-594-3215.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Tracy L. Acker, Center for Drug Evaluation and Research (HFD-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2831, or via Internet at ackert@cder.fda.gov.

Regarding biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM-202), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3028, or via Internet at stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled “Accelerated Approval Products: Submission of Promotional Materials.” This draft guidance is intended to assist sponsors of drug and biological products who are submitting promotional materials as part of the accelerated approval process.

In the **Federal Register** of December 11, 1992 (57 FR 58942), FDA published final regulations under which the agency would accelerate the approval of certain new drugs and biological products for serious or life-threatening illnesses. In November 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Pub. L. 105-115). Section 112 of the Modernization Act, in part, essentially codified in statute the accelerated approval regulations in an amendment to the Federal Food, Drug, and Cosmetic Act (section 506 of the act (21 U.S.C. 356) entitled “Fast Track Products”). On November 12, 1998, FDA published a draft guidance for industry on its policies and procedures regarding fast track drug development programs. The draft guidance that is the subject of this notice would apply to all products approved under § 314.500 (21 CFR 314.500), including those designated as fast track development programs.

Among other things, the accelerated approval regulations (§§ 314.550 and 601.45 (21 U.S.C. 314.550 and 601.45)) require that applicants, unless otherwise informed by the agency, submit

to FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication during the 120 days following marketing approval. The accelerated approval regulations also require that promotional materials intended for use following the 120-day postapproval period must be submitted to FDA for review at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement, unless otherwise informed by the agency.

During the past several years, representatives of the pharmaceutical industry have requested guidance from FDA on the procedures for submitting promotional materials under §§ 314.550 and 601.45. The draft guidance is intended to assist applicants submitting promotional materials under these regulations.

This draft guidance document represents the agency's current thinking on the process for submitting promotional materials for accelerated approval 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 requirement of the applicable statute, regulations, or both.

Interested persons may, on or before (*insert date 60 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments or requests for copies 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 19, 1999

March 19, 1999



William K. Hubbard
Acting Deputy Commissioner for Policy

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