

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 314

[Docket Nos. 99N-0193 and 99D-0529]

Changes to an Approved NDA or ANDA; Proposed Rule and Draft Companion Guidance; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss proposed amendments to its regulations on postapproval changes to the chemistry, manufacturing, and controls of approved drugs, and a draft companion guidance. FDA is inviting interested parties, including industry, health professionals, patients, and patient advocacy groups to present their perspectives on the proposed amendments and the draft companion guidance.

DATES: The meeting will be held on Thursday, August 19, 1999, from 9 a.m. to 5 p.m. Registration and requests to make an oral presentation should be received by Monday, August 13, 1999.

ADDRESSES: The meeting will be held at the Hilton Hotel, 620 Perry Pkwy., Gaithersburg, MD. To register and request time for an oral presentation, send or fax written material to the listed contact person.

FOR FURTHER INFORMATION CONTACT: Susan C. Lange, Office of New Drug Chemistry (HFD-800), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5918, FAX 301-594-0746.

SUPPLEMENTARY INFORMATION: Section 116 of the Food and Drug Administration Modernization Act of 1997 provides for the revision of § 314.70 (21 CFR 314.70) of FDA regulations concerning

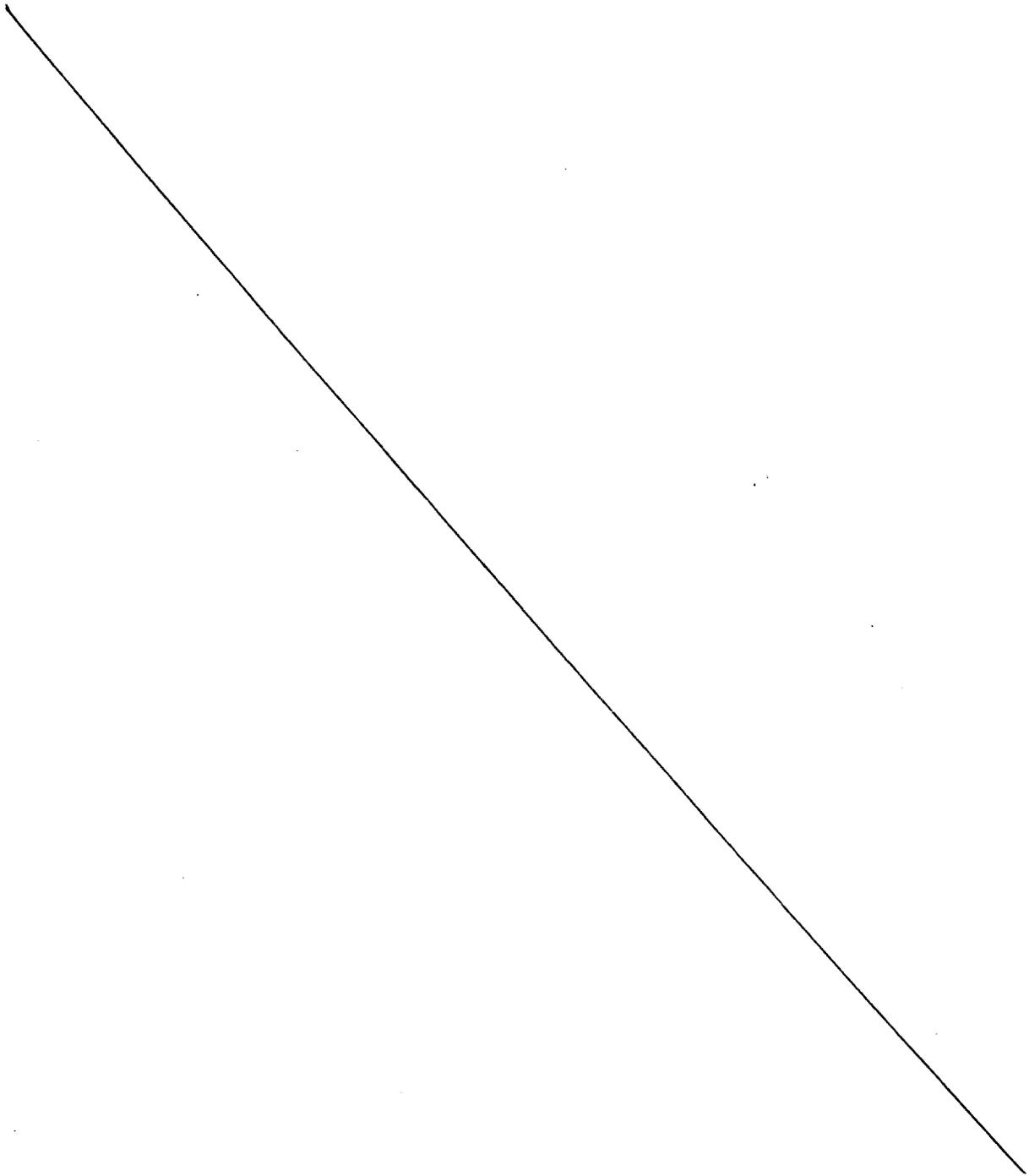
postapproval changes to the chemistry, manufacturing, and controls of approved drugs. In the **Federal Register** of June 28, 1999 (64 FR 34608), the agency published a proposed rule entitled “Supplements and Other Changes to an Approved Application,” proposing amendments to § 314.70. The comment period for the proposed rule closes on September 13, 1999 (Docket No. 99N-0193). In the same issue of the **Federal Register** (64 FR 34660), the agency announced the availability of a draft guidance for industry entitled “Changes to an Approved NDA or ANDA.” The comment period for the draft guidance closes on August 27, 1999 (Docket No. 99D-0529). To ensure broad public input on the proposed rule and the draft guidance, the agency is holding a public meeting on the proposed amendments to § 314.70 and the draft guidance for industry.

To provide a framework for presentations, discussions of revisions to § 314.70 will be organized according to the following sections in the proposed regulation: (1) Section 314.70(a)—Changes to an approved application; (2) § 314.70(b)—Changes requiring a prior approval supplement; (3) § 314.70(c)—Changes being effected supplement; (4) § 314.70(d)—Changes for description in an annual report; and (5) § 314.70(e)—Protocols.

The presentation topics for the draft guidance will be organized as follows: (1) Assessing the effect of manufacturing changes; (2) components and composition; (3) sites; (4) manufacturing process; (5) specifications; (6) package; (7) labeling; (8) miscellaneous changes; and (9) multiple changes.

When submitting a request for an oral presentation at the August 19, 1999, meeting, please specify your presentation topic. The time allowed for each presenter will depend on the number of presentation requests.

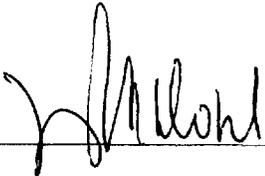
Registration information (including name, title, firm name, address, telephone, and fax number) and requests for presentation (including specific topic) should be submitted to the listed contact person by Friday, August 13, 1999. Space is limited, therefore, interested parties are encouraged to register early. Special accommodations due to disability should be submitted at least 7 days in advance.



Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: 7/28/99

July 28, 1999



Margaret M. Dotzel
Acting Associate Commissioner
for Policy

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