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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 98 D-0997]

Draft Guidance for Industry on Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation.” This draft document provides guidance for industry on the chemistry, manufacturing, and controls (CMC) documentation to be submitted in new drug applications (NDA’s) and abbreviated new drug applications (ANDA’s) for metered dose inhalation aerosols, metered dose nasal aerosols, and inhalation powders.

DATES: Written comments may be submitted on the draft guidance document by (insert *date* 90 *days after date of publication in the Federal Register*).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ADDRESSES: Copies of this draft guidance are available on the Internet at ‘ [http://www.fda.gov/cder/guidance/index .htm](http://www.fda.gov/cder/guidance/index.htm). ’ Written requests for single copies of the draft guidance should be submitted to the Drug Information Branch (HFD-2 10), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rrm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Guirag Poochikian, Center for Drug Evaluation and Research (HFD-570), Food and Drug Administration, 5600 Fishers Lane, rm. 10 B45, Rockville, MD 20857, 301-827-1050.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products: Chemistry, Manufacturing, and Controls Documentation." This draft guidance sets forth information that should be provided to ensure continuing drug product quality and performance characteristics for MDI's and DPI's. In addition to providing guidance on CMC documentation to be submitted in NDA's and ANDA's for DPI's and MDI's, the draft guidance covers CMC information recommended for inclusion in the application with regard to the components, manufacturing process, and the controls associated with each of these areas. The document does not address inhalation solutions or aqueous nasal sprays.

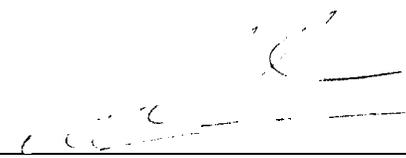
FDA intends to sponsor a public meeting in 1999 on MDI and DPI drug products. The comments submitted on this draft guidance will be used to help develop the agenda for this meeting.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on CMC documentation to be submitted in NDA's and ANDA's for metered dose inhalation aerosols, metered dose nasal aerosols, and inhalation powders. 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 submit written comments on the draft guidance to the Dockets Management Branch (address above). 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 1998
November 13, 1998



William K. Hubbard
Associate Commissioner for Policy Coordination

[FR Dec. 98-'??'?! Filed '?'-'?'-'98; 8:45 am]

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