

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0510]

DMB

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Certifier	R. LEDESMA

Draft Guidance for Industry on Integration of Dose-Counting Mechanisms into MDI Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Integration of Dose-Counting Mechanisms into MDI Drug Products." This draft guidance makes recommendations to manufacturers to incorporate dose-counters into metered-dose inhalers (MDIs) being developed for the treatment of lung diseases. The recommendations made in this draft guidance are intended to enhance the use of MDIs, specifically to help patients identify when MDIs are no longer delivering reliable doses.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Sandra L. Barnes, Center for Drug Evaluation and Research (HFD-570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1050.

SUPPLEMENTARY INFORMATION:

I. Background

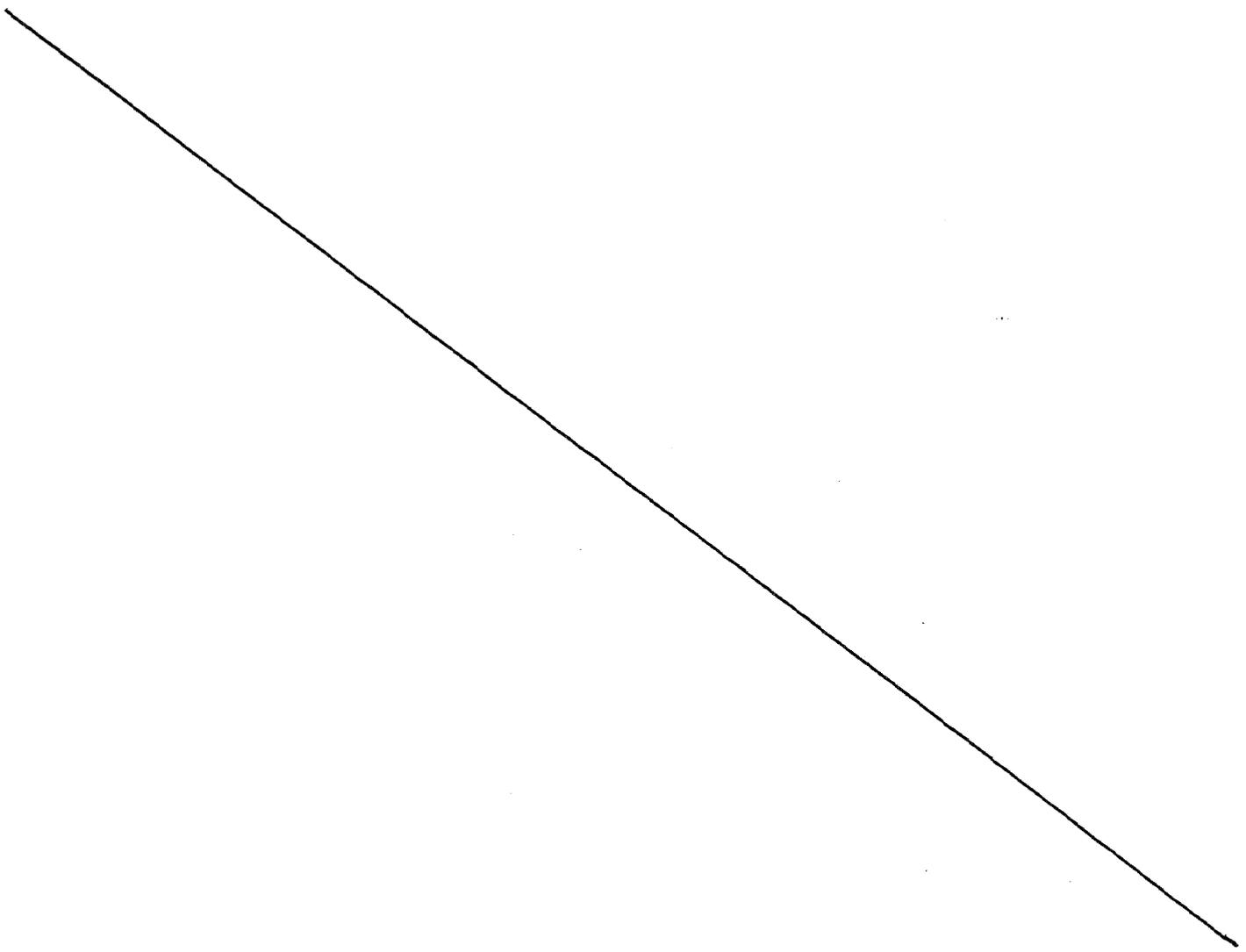
FDA is announcing the availability of a draft guidance for industry entitled “Integration of Dose-Counting Mechanisms into MDI Drug Products.” It is intended primarily for manufacturers of MDI drug products designed to deliver drugs to the lungs (e.g., an MDI for the treatment of asthma). Dose-counters are mechanisms designed to accurately track the number of actuations used by a patient over the life span of an individual MDI. The dose-counter would provide the patient with continuing, accurate data on the amount of medication left in the MDI. Currently, patients do not have an adequate way to track the number of metered-doses left in MDIs, and there is no way to detect when these devices have exceeded their dose limit. The incorporation of a reliable, accurate dose-counter into each MDI will enhance these drug products, which are relied on to deliver important and sometimes life-saving drugs to patients with asthma and other obstructive lung diseases.

This 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 the integration of dose-counting mechanisms into MDI drug 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,

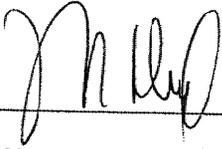
except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through 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/ohrms/dockets/default.htm>.

Dated: 12/3/01
December 3, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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