

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB  
Display Date 3-12-03  
Publication Date 3-13-03  
Certifier SPrese

[Docket No. 03D-0043]

**Guidance for Industry on Integration of Dose-Counting Mechanisms into Metered-Dose Inhaler Drug Products; 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 "Integration of Dose-Counting Mechanisms into MDI Drug Products." This guidance is intended to assist manufacturers who are developing or plan to develop drug products for oral inhalation using metered-dose inhalers (MDIs).

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

**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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 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 guidance document.

cd02148

03D-0043

NAD-1

**FOR FURTHER INFORMATION CONTACT:** Sandy Barnes, Center for Drug Evaluation and Research (HFD-570), Food and Drug Administration, 5600 Fishers Lane, rm. 8B-45, Rockville, MD 20857, 301-827-1055.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

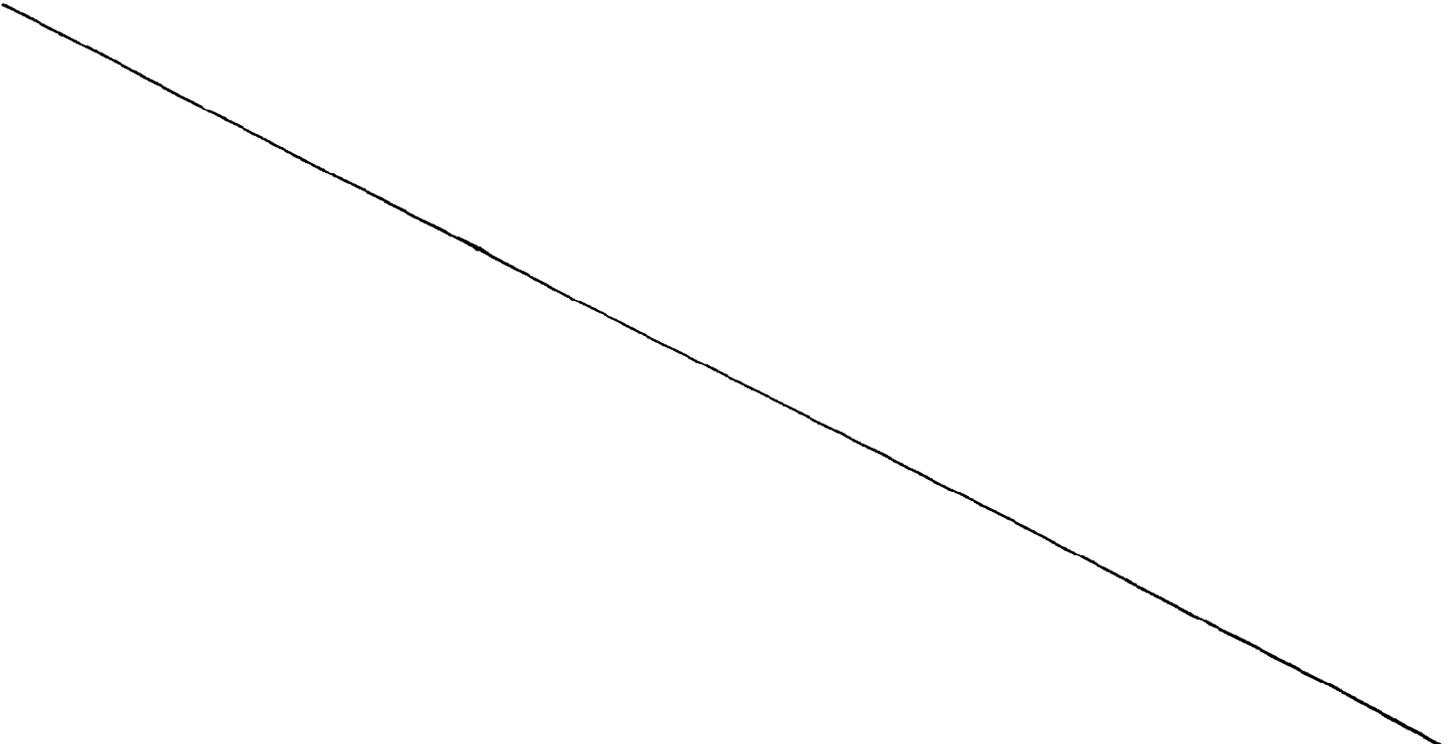
FDA is announcing the availability of a guidance for industry entitled “Integration of Dose-Counting Mechanisms into MDI Drug Products.” This guidance is intended to assist manufacturers who are developing or plan to develop drug products for oral inhalation using MDIs. The guidance reflects the agency’s current recommendations regarding the integration of dose-counting mechanisms into MDI drug products for oral inhalation. Although the contents of the guidance should be considered by any manufacturer of any MDI drug product (including nasal MDI products), this guidance is neither specifically intended for manufacturers of already marketed MDI drug products for oral inhalation nor for manufacturers developing MDIs for other routes of administration (e.g., nasal MDIs). It is also not intended for manufacturers developing multidose dry powder inhalers (MDPIs), which already incorporate dose counters as an integral part of the delivery system. Manufacturers developing new MDPIs are encouraged to continue including dose counters in their delivery systems and may find the contents of this guidance useful in their planning.

A draft guidance of the same name was made available for public comment in a notice published in the **Federal Register** of December 11, 2001 (66 FR 64045). This guidance contains only clarifying editorial changes.

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 integrating 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, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of any mailed 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 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: March 5, 2003  
March 5, 2003.

William K. Hubbard  
William K. Hubbard,  
Associate Commissioner for Policy and Planning.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

Scott M. Case