

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1454]

DMB
Display Date 7-3-02
Publication Date 7-5-02
Certifier R. LEDESMA

Guidance for Industry on Nasal Spray and Inhalation Solution, Suspension, and Spray 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 guidance for industry entitled “Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation.” This document provides guidance for industry on the chemistry, manufacturing, and controls documentation that should be submitted in new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for nasal spray and inhalation solution, suspension, and spray drug products intended for local and/or systemic effect. The guidance also provides recommendations on labeling.

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.

FOR FURTHER INFORMATION CONTACT: Guirag Poochikian, 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 guidance for industry entitled "Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation." This guidance provides recommendations on the information that should be submitted in NDAs and ANDAs for these products, including information on drug product components, manufacturing process, and the associated controls. However, it does not address the manufacture of drug substances. The guidance gives recommendations on information that should be provided to ensure continuing quality and performance characteristics for these drug products. This guidance also provides information on labeling.

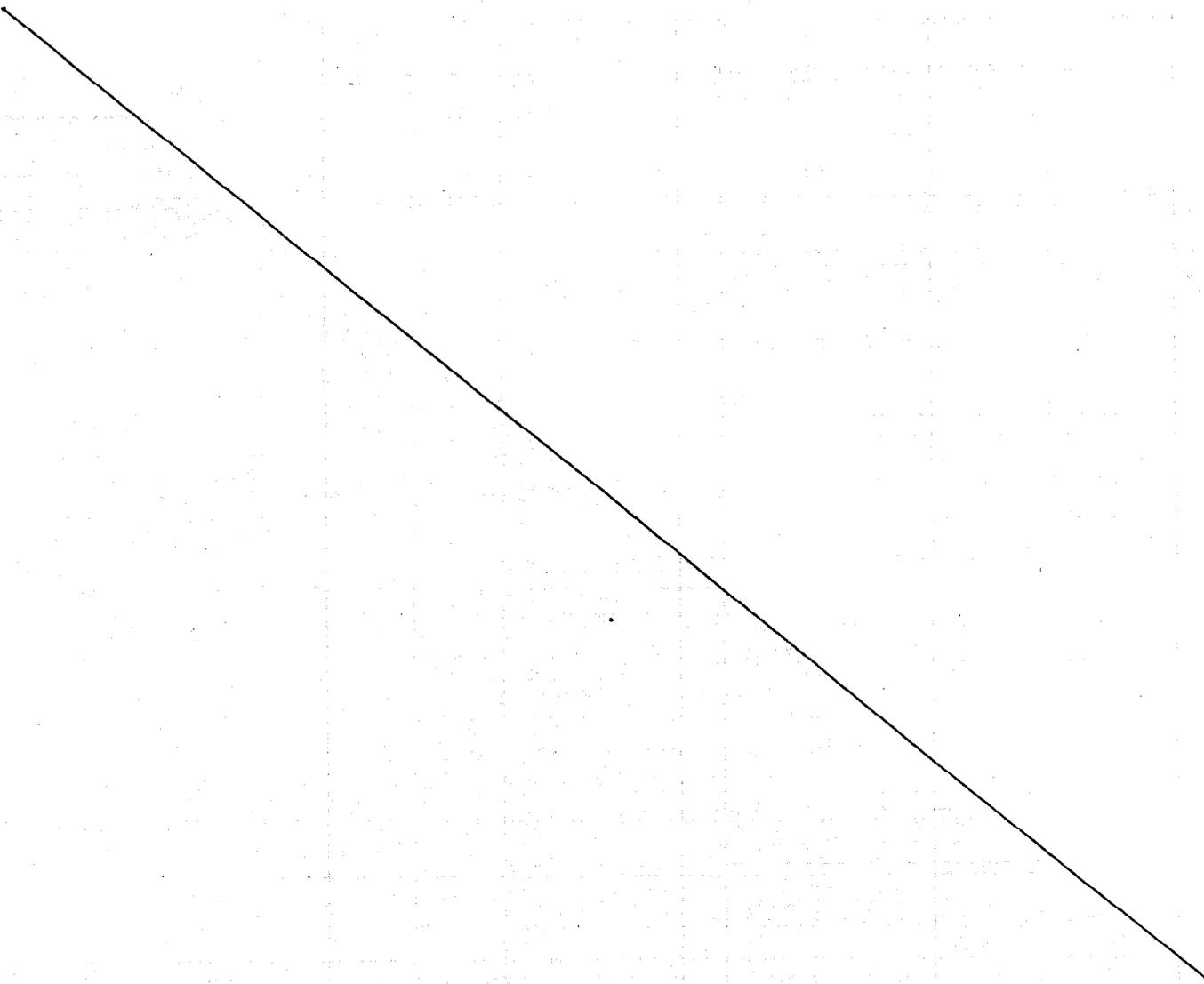
In the **Federal Register** of June 2, 1999 (64 FR 29657), FDA announced the availability of a draft version of this guidance. The June 1999 guidance gave interested persons an opportunity to submit comments through August 31, 1999. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of the public comment, the guidance is clearer and more concise than the draft version. FDA is participating in research relating to these types of drug products through the Product Quality Research Institute (Internet address at <http://www.pqri.org>) and will evaluate whether to update the guidance as information from this research becomes available.

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 chemistry, manufacturing, and controls documentation for nasal spray and inhalation solution, suspension, and spray 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 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.

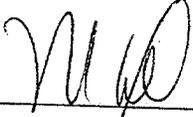


III. Electronic Access

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: 6/24/02

June 24, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

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

