

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 99D-1454]

Draft Guidance for Industry on Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products; Chemistry, Manufacturing, and Controls Documentation; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products; Chemistry, Manufacturing, and Controls Documentation." This draft document is intended to provide 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 nasal spray and inhalation solution, suspension, and spray drug products. This draft guidance also covers CMC information recommended for inclusion in the NDA's and ANDA's regarding the components, manufacturing process, and associated controls with each of these areas.

DATES: Written comments on the draft guidance may be submitted by August 31, 1999. 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ADDRESSES: Copies of this draft guidance are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm". Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products; Chemistry, Manufacturing, and Controls Documentation." This draft guidance sets forth information that should be provided to ensure continuing quality and performance characteristics for these drug products.

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 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 statute, regulations, or both.

Interested persons may, on or before August 31, 1999, submit to the Dockets Management Branch (address above) written 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 25, 1999.

William K. Hubbard,
Associate Commissioner for Policy Coordination.

[FR Doc. 99-13921 Filed 6-1-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Care Financing Administration**

[Document Identifier: HCFA-R-281]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment.

Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. The HCFA-R-281 will be used to evaluate the effects of the "Medicare and You Handbook: 2000" to determine that beneficiaries not only received it and are aware of the information, but whether they understand the information and are able to use it in making informed choices about their Medicare plan. Without this information, HCFA would not be able to obtain the information necessary to determine whether these goals have been met. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result due to the possibility of beneficiaries not being properly informed/educated as to the importance of their Medicare plan choices.

HCFA is requesting OMB review and approval of this collection by 6/14/99, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below, by 6/10/99. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New Collection.

Title of Information Collection: Survey of Medicare Beneficiaries for the