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Draft Guidance for Industry on Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products; Chemistry, Manufacturing, and Controls Documentation; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products; Chemistry, Manufacturing, and Controls Documentation.''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 This draft guidance also covers CMC information recommended for inclusion in the NDA's and ANDA's regarding the components, manufacturing process, and associated controls with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DATES: Written comments on the draft guidance may be submitted by August 31, 1999.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ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products; Chemistry, Manufacturing, and Controls Documentation.'' This draft guidance sets forth information that should be provided to ensure continuing quality and performance characteristics for these drug products.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]

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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

National ''Medicare and You Handbook: 2000'' Evaluation.

Form No.: HCFA–R–281 (OMB 0938–NEW).

Use: As part of the National Medicare Education Program (NMEP), HCFA plans a national mailing of the Medicare & You 2000 handbook to the entire Medicare population in September 1999. To evaluate the effects of the handbook, HCFA needs to know not only that beneficiaries 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.

To quantify whether these goals have been met, measures of what beneficiaries currently know and understand about the Medicare program must be established. It is also necessary to compare attitudes and behavior of beneficiaries who receive the information to those who do not to determine if the print campaign of the NMEP (Medicare & You handbook) has been effective.

This survey will be used to determine the effectiveness of the ''Medicare and You Handbook: 2000''.

Frequency: Other: one time.

Affected Public: Business or other for-profit, and Individuals or Households.

Number of Respondents: 4,000.

Total Annual Responses: 4,000.

Total Annual Hours: 2,950.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of Information requirements. However, as noted above, comments on these Information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by 6/10/99:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850
and
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167, Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: May 20, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–13870 Filed 6–1–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Organ Procurement and Transplantation Network (OPTN) Data System (OMB No. 0915–0157)—Revision

This is a request for revision of the data system for the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR) and the following associated forms: (1) cadaver donor registration/referral; (2) living donor registration; (3) donor histocompatibility; (4) potential recipient form; (5) recipient histocompatibility; (6) transplant candidate registration; (7) thoracic organ recipient registration; (8) thoracic organ recipient follow-up; (9) kidney transplant recipient registration; (10) kidney transplant recipient follow-up form; (11) liver transplant recipient registration; (12) liver transplant recipient follow-up; (13) pancreas transplant recipient registration; (14) pancreas transplant recipient follow-up; (15) intestine transplant recipient registration; and (16) intestine transplant recipient follow-up. New forms are related to intestine transplants to collect data similar to other types of transplants.

The estimated respondent burden is as follows:

	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Cadaveric Registration or Referral	65	277	0.3	5,400
Living Donor Registration	680	7	0.2	920
Living Donor Follow-up	680	14	0.1	952
Donor Histocompatibility	159	75	0.1	1,200
Potential Recipient Form	65	385	0.3	7,500
Recipient Histocompatibility	159	157	0.1	2,500
Transplant Candidate Registration	387	114	0.2	15,600
Thoracic Registration	153	27	0.3	1,230
Thoracic Follow-up	153	144	0.2	4,400
Kidney Registration	252	58	0.3	4,380
Kidney Follow-up	252	500	0.2	25,200
Liver Registration	125	40	0.4	2,000