The NCHSTP anticipates that the role of the successful collaborator(s) will include the following:

(1) Providing intellectual, scientific, and technical expertise and experience to the research project;

(2) Participating in the planning of research studies, interpretation of research results, and as appropriate, joint publication of conclusions;

(3) Providing NCHSTP access to necessary proprietary technology and/or data in support of the research activities; and

(4) Providing NCHSTP clinical grade (c-GMP) agent for use in preclinical and clinical studies covered in this collaboration.

Other contributions may be necessary for particular proposals.

Selection Criteria

In addition to evidence of the ability to fulfill the roles described above, proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

(1) Data on the in-vitro anti-HIV activity of the agent;

(2) Animal and other data on the safety of the agent when applied to mucosal surfaces;

(3) Data on the effects of the agent on vaginal and/or rectal commensal microbial organisms; and

(4) Data on the in-vitro activity of the agent against other sexually transmitted organisms.

Dated: May 14, 2004.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 04–11402 Filed 5–19–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0221]

Medicare Prescription Drug, Improvement, and Modernization Act of 2003; Study on Making Prescription Pharmaceutical Information Accessible for Blind and Visually-Impaired Individuals; Establishment of Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a docket to receive information and comments on certain issues related to the accessibility of pharmaceutical information to blind and visually-impaired individuals. This action is intended to ensure that there is a venue for information and comments to be communicated to the agency for consideration in a study on making prescription drug information accessible for blind and visually-impaired individuals, which was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act).

DATES: The agency encourages interested parties to submit information and comments by June 21, 2004.

ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Poppy Kendall, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, e-mail: *poppy.kendall@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 2003, President Bush signed the Medicare Modernization Act (Public Law 108–173). Section 107(f) of this legislation requires that the Secretary of Health and Human Services undertake a study on how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually-impaired individuals. The legislation requires that the study ''include a review of existing and emerging technologies, including assistive technology, that makes essential information on the content and prescribed use of pharmaceutical medicines available in a usable format for blind and visually-impaired individuals.''

II. Request for Comments

To assist in this effort, we are asking for public comment on the following issues:

A. Information About the Population of Interest:

1. What is known about the population of people who are blind and visually-impaired in the United States (e.g., information on age of onset; cause of impairment (e.g., congenital defect versus disease-related versus injury); extent and type of impairment; association between visual impairment and age, hearing loss, comorbidities, health outcomes, socioeconomic status, health literacy, and adaptive learning capabilities)?

2. Is there an appropriate way to divide this population into subpopulations to better evaluate needs and beneficial technologies?

B. Information About the Use of Prescription Medication Information By People Who Are Blind or Visually-Impaired:

1. How do people who are blind and visually-impaired currently get their prescription drug information?

2. What aspects of visual impairment are important to addressing the issue of access to prescription drug information? What other factors (see examples listed in Question #A1) might be important to addressing this issue?

3. How can essential drug information be effectively communicated to people who are blind or visually impaired?

4. Are there data associating medication errors with blindness? With visual impairment? What types of medication errors are most common among people who are blind or visually impaired?

C. Information About Existing and Emerging Technologies (Including Internet-based Information Sources):

1. What assistive technologies are currently used by people who are blind or visually-impaired? In what setting?

2. What proportion of people who are blind and visually-impaired currently use these technologies? Are there specific characteristics (see examples listed in Question #A1) of this ''user'' population that distinguish them from blind and visually-impaired individuals who do not use these technologies?

3. Are there data on the effectiveness of these technologies?

4. Do these technologies contribute to an increase or decrease in medication errors reported amongst people who are blind or visually impaired?

5. What is the cost of these technologies?

6. Who are the primary purchasers of these technologies? Is use of these technologies currently subsidized by any government or private program?

7. What are barriers to use of these assistive technologies?

8. What is the practicability of these assistive technologies?

9. How do people who are blind or visually-impaired learn of these technologies?

9a. What are the most effective resources for conveying information about these assistive technologies to blind and visually impaired individuals.

10. Are there emerging technologies that show promise? If so, what is the

anticipated cost and timeline for market entry?

III. Submission of Comments

All comments submitted to the public docket are public information and may be posted to FDA's Web site at: *http://www.fda.gov* for public viewing. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11365 Filed 5–19–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0468]

Guidance for Industry on the Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry (#122) entitled ''Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores.'' The purpose of this document is to provide guidance on the manufacture and labeling of foods that contain raw meat, or other raw animal tissues, for consumption by dogs, cats, other companion or pet animals, and captive noncompanion animal carnivores and omnivores.

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

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http:///www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance document and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: William Burkholder, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0179, e-mail: *William.burkholder@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 18, 2002 (67 FR 77500), FDA published a notice of availability for a draft guidance entitled ''Draft Guidance for Industry on Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores.'' FDA gave interested persons until March 3, 2003, to comment. FDA considered all comments received and, where appropriate, incorporated them into the guidance.

II. Paperwork Reduction Act of 1995

According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. This guidance contains no collections of information.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking about the manufacture and labeling of raw meat foods for companion and captive noncompanion carnivores and omnivores. It does not create or confer any rights for or on any person and will 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.

IV. Comments

As with all of FDA's guidance, the public is encouraged to submit written or electronic comments on this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance.

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this site, select [2002D–0468] ''Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores'' and follow the directions. Copies of this guidance may be obtained on the Internet at *http://www.fda.gov/cvm/guidance/published.htm*.

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11366 Filed 5–19–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Guidance and Forms for the Title V Section 510 Abstinence Education Grant Program Application/Annual Report—NEW

The Application Guidance for Section 510 of the Social Security Act is used annually by all States and jurisdictions in applying for Abstinence Education Block Grants under Section 510 of Title