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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 *[insert date 30 days after date of publication in the Federal Register]*.

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?

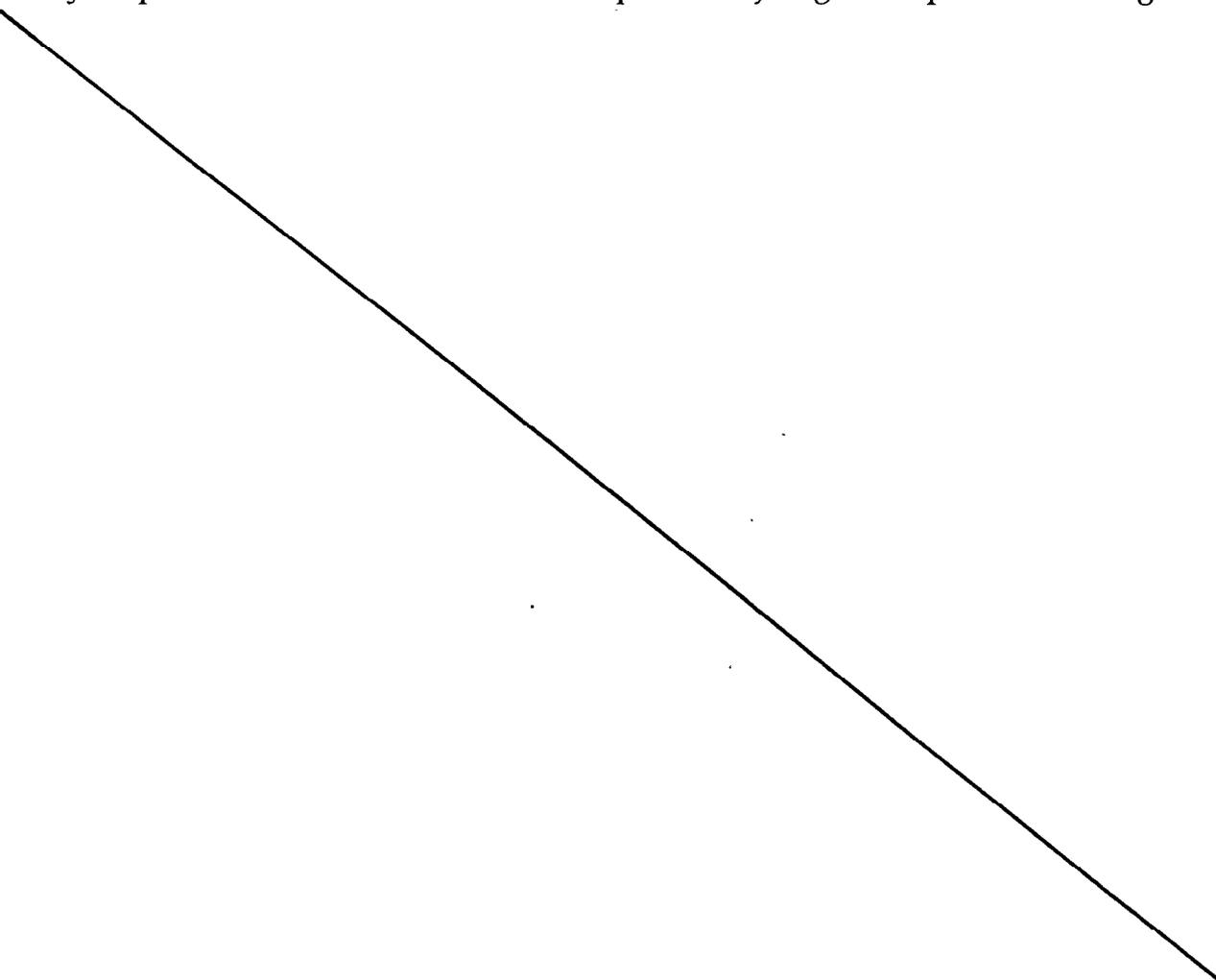
9. How do people who are blind or visually-impaired learn of these technologies?

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
May 12, 2004.



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

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