Medical Devices: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use—Section 502 of the Federal Food, Drug and Cosmetic Act/Section 351 of the Public Health Service Act (OMB Control Number 0910–0553)—Extension

Section 502 of the Federal Food, Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded. Section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), establishes requirements that manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product for introduction into interstate commerce.

In the **Federal Register** of November 30, 2004 (69 FR 69606), FDA published a notice of availability of the guidance entitled ''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use.'' The guidance document provides guidance for the voluntary use of selected symbols in place of text in labeling. It provides the labeling guidance required for: (1) In vitro diagnostic devices (IVDs), intended for professional use under 21 CFR 809.10, FDA's labeling requirements for IVDs and (2) FDA's labeling requirements for biologics, including IVDs under 21 CFR parts 610 and 660. Under section 502(c) of the FFD&C Act, a drug or device is misbranded, ''If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' The guidance document recommends that a glossary of terms accompany each IVD to define the symbols used on that device's labels and/or labeling. Furthermore, the guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and educational outreach information will help to ensure that IVD users will have enough general familiarity with the symbols used, as well as provide a quick reference for available materials, thereby further ensuring that such labeling satisfies the labeling requirements under section 502(c) of the act and section 351 of the PHS Act.

The likely respondents for this collection of information are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 502 of the FFD&C Act/Section 351 of the PHS Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	1,742	1	1,742	4	6,968[2]
Educational Outreach	1,742	1	1,742	6	27,872
Total					34,840

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.

The glossary and educational outreach activities are inclusive of both domestic and foreign IVD manufacturers. The Center for Devices and Radiological Health's ''Information Retrieval System's Registration and Listing Information'' database listed the total number of IVD manufacturers as 1,742. From this total, 1,206 of the IVD manufacturers were listed as domestic and 536 were listed as foreign manufacturers. Consequently, FDA has based its burden estimate on the maximum possible number of manufacturers choosing to implement the use of symbols in labeling. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary for the specific symbols used in labels or labeling for the IVDs manufactured. The 16-hour estimate for educational outreach is inclusive of activities manufacturers used to educate the various professional users of IVDs regarding the meaning of the IVD symbols. Further, this estimate is based on FDA's expectation that IVD manufacturers will jointly sponsor many more educational outreach activities.

Dated: August 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0330]

Presidential Interagency Working Group on Import Safety; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Interagency Working Group on Import Safety (Working Group) is announcing a public meeting to identify actions the public and private sectors can take to promote the safety of products imported into the United States. The Working Group was created by the Executive order on July 18, 2007.

DATES: The public meeting will be held on October 1, 2007, from 8 a.m. to 6 p.m. Persons interested in attending the meeting in person or by teleconference must register by September 17, 2007. See section III.B of the **SUPPLEMENTARY INFORMATION** section of this document for details on how to register. Submit written or electronic comments by October 1, 2007.

ADDRESSES: The public meeting will be held in the Jefferson Auditorium, U.S. Department of Agriculture, 1400 Independence Ave., SW., South Bldg., Washington, DC 20090. The public may

also attend or present at the meeting by teleconference (audio bridge).

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: For information regarding the meeting or this notice: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777, e-mail: *erik.mettler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Working Group was established by Executive Order 13439 on July 18, 2007, to conduct a comprehensive review of current import safety practices and determine where improvements can be made. The Working Group, chaired by the Department of Health and Human Services' Secretary Michael O. Leavitt, is comprised of officials from the Department of Health and Human Services; the Department of State; the Department of the Treasury; the Department of Justice; the Department of Agriculture; the Department of Commerce; the Department of Transportation; the Department of Homeland Security; the Office of Management and Budget; the Office of the United States Trade Representative; the Environmental Protection Agency; and the Consumer Product Safety Commission.

The mission of the Working Group is to identify actions and appropriate steps that can be pursued, within existing resources, to promote the safety of imported products, including the following:

(1) Reviewing or assessing current procedures and methods aimed at ensuring the safety of products exported to the United States; these current procedures and methods include: Reviewing existing cooperation with foreign governments, foreign manufacturers, and others in the exporting country's private sector regarding their inspection and certification of exported goods and factories producing exported goods; and considering whether additional initiatives should be undertaken with respect to exporting countries or companies;

(2) Identifying potential means to promote all appropriate steps by U.S. importers to enhance the safety of imported products, including identifying best practices by U.S. importers in selection of foreign manufacturers, inspecting manufacturing facilities, inspecting goods produced on their behalf either before export or before distribution in the United States, identifying origin of products, and safeguarding the supply chain; and

(3) Surveying authorities and practices of Federal, State, and local government agencies regarding the safety of imports to identify best practices and enhance coordination among agencies.

The Working Group plans to release a Strategic Framework to promote import safety and deliver this report to the President by the September 17, 2007, due date (see **DATES**). The Working Group plans to release a followup Action Plan by mid-November 2007. This Action Plan will take into consideration the feedback received from the public, and recommend specific actions the Federal Government and all parties involved can take to enhance import safety on all levels.

II. Purpose of the Public Meeting

The objective of the Import Safety public meeting, to be held on October 1, 2007, is to identify and recommend actions that persons involved in the production, distribution, importation, regulation, and use of imported products, including government, industry, and consumers can take to promote the safety of such products.

To help achieve this objective, the Working Group would like public comments to address the following questions:

1. What are the key challenges for industry, consumers, and foreign, State and local governments to ensure the safety of products imported into the United States?

2. Consistent with the Strategic Framework, the Working Group will recommend to the President by September 17, 2007, what actions should persons involved in the production, distribution, importation, regulation, and use of imported products, including Federal, State, local and foreign governments, manufacturers, distributors, brokers, importers, and consumers take, individually or jointly, to promote the safety of imported products? What should the Federal government and others do to implement or facilitate the implementation of these actions?

3. For each action, what is the benefit(s) of implementing this recommendation? What is the cost(s) of implementing this recommendation? What challenge(s) does it address? Are there other actions that must or should be taken first before implementing this recommendation?

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will We Use?

Through this document, we are announcing the convening of a public meeting to hear recommendations on actions that can be taken to promote import safety. Representatives from member Departments of the Working Group will preside over the meeting.

We will conduct the meeting on October 1, 2007, in the Jefferson Auditorium (see **ADDRESSES**). The meeting format will include presentations by persons registered to speak.

B. How Do You Register for the Meeting or Submit Comments?

If you wish to attend the meeting in person or by teleconference and/or make a presentation at the meeting, send an e-mail message to Erik Mettler (see **FOR FURTHER INFORMATION CONTACT**) by close of business on September 17, 2007. Your e-mail should include the following information: Name, company, company address, company telephone number, e-mail address, whether you will attend the meeting in person or by teleconference, and whether you wish to speak at the meeting. We will send you a confirmation within 2 business days after we receive your registration request. Registration is free and will be on a first-come, first-serve basis.

We also will accept walk-in registration at the meeting site, but space is limited, and we will close registration when maximum seating capacity (approximately 500) is reached.

We will try to accommodate all persons who wish to speak. The time allotted for presentations may depend on the number of persons who wish to speak. Individuals will be able to make a presentation at the meeting either in person or by teleconference.

Additionally, regardless of whether you wish to make a presentation or simply attend the meeting, contact Erik Mettler (see **FOR FURTHER INFORMATION CONTACT**) if you need any special accommodations (such as wheelchair access or a sign language interpreter).

If you would like to submit electronic or written comments, please send your comments to the Division of Dockets

Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Written or electronic comments must be received no later than (see **DATES**).

C. Will Meeting Transcripts Be Available?

We will prepare a meeting transcript and make it available on FDA's Web site (*http://www.fda.gov/ohrms/dockets*) after the meeting. We anticipate that transcripts will be available approximately 21 business days after the meeting. The transcript will also be available for public examination at the Division of Dockets Management (see **ADDRESSES**).

Dated: August 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; National Physician Survey of Practices on Diet, Physical Activity, and Weight Control

SUMMARY: Under the provision of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), National Cancer Institute (NCI), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 28, 2007, page 43609 and allowed 60-days for public comment. One public comment was received asking about the possibility of doing studies of autism rather than the proposed survey. The comment was out of the scope of this current project. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Physician Survey of Practices on Diet, Physical Activity, and Weight Control.

Type of Information Collection Request: NEW.

Need and Use of Information Collection: This study will obtain current, national data on primary care physicians' knowledge, attitudes, and practices related to diet, physical activity, and weight control. Obesity, poor diet, and lack of physical activity are becoming recognized as major public health problems in the United States, and have been linked to increased risk, adverse prognosis, and poor quality of life for cancer and many other chronic diseases. The data collected in this study will support and further NCI work in monitoring and evaluating providers' cancer prevention knowledge, attitudes, and practices and their impact on pupulation health, as well as enable monitoring of progress toward major cancer control goals. Data from the survey will be used to profile existing physician practice, understand barriers to counseling and referral, and to inform methods for improving the utilization of these services for adults and children. Two questionnaires, one sent to physicians and one sent to their practice administrators, will be administered by mail or telephone to a randomly-selected national sample of 2,000 physicians belonging to primary care specialties. Study participants will be 2,000 practicing physicians who are family practitioners, general internists, pediatricians, and obstetrician/gynecologists and 2,000 practice administrators.

The annual reporting burden is as follows: *Estimated Number of Respondents:* 4,000; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .333; and *Estimated Total Annual Burden Hours, Requested:* 1,332. The annualized cost to respondents is estimated at: $65,048. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondent	Estimated number respondents	Estimated number responses per respondent	Average burden hours per response	Estimated total annual burden hours
Physician	2,000	1	0.333	666
Medical Practice Administrator	2,000	1	0.333	666
Total	4,000	1		1,332

* Hourly earnings data are taken from the National Compensation Survey: Occupational Wages in the United States, June 2005, U.S. Department of Labor, U.S. Bureau of Labor Statistics.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (a) Whether the proposed collection of information is necessary for the 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.

FOR FURTHER INFORMATION CONTACT: Send comments to Ashley Wilder Smith, Ph.D., M.P.H., Health Sciences Specialist, National Cancer Institute, 6130 Executive Blvd., MSC 7344, Executive Plaza North, Room 4090, Bethesda, MD 20892–7344. Telephone: 301–451–1843; E-mail: *smithas@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of