

current ICH guidances. FDA agrees with these comments and the “Not Serious” and “No Harm” checkboxes do not appear on the final Form FDA 3500 and Form FDA 3500A. Another proposed checkbox was “Important Medical Events”. This checkbox has been revised on the final Form FDA 3500 and Form FDA 3500A to “Other Serious (Important Medical Events)”. This new terminology is consistent with the definition of “Serious” in 21 CFR 310.305, 312.32, 314.80, and 600.80 as well as ICH E2A guidelines. In addition, the outcome “Required Intervention to Prevent Permanent Impairment/Damage” has been revised, adding “(devices)” at the end of the term. Additional detail has been provided in the revised instructions to provide more clarity for the use of section B.2 of both forms.

In section B.5 of both forms, the proposed checkboxes “Product Used During Pregnancy” and “Product Used During Breast Feeding” produced concern as these new data fields introduce divergence from ICH standards and appear to duplicate information that is usually provided in the narrative section and in coded adverse event terms. FDA agrees and has not included these checkboxes in the final forms. As a result, the term “Pregnancy” has been returned to the examples in section B.7 (Other Relevant History) on both Form FDA 3500 and Form FDA 3500A.

A few comments noted the removal of the term “if known” from several fields of the forms and questioned this action as a new requirement for these data. The final forms do not contain the term “if known” in any of the fields for reasons of form consistency. This should not be interpreted as a new requirement. If information is not known for any of the fields, they should be left blank. This is reflected in the revised instructions.

Several comments questioned the addition of the Unique Identifier Number (Unique ID) to proposed section D.9 of both forms. Unique ID is required under § 1271.350 for reporting of adverse events for HCT/Ps.

One comment recommended the addition of “Solicited” and “Spontaneous” checkboxes to Form FDA 3500A. FDA has not accepted this recommendation. As described in an August 1997 guidance for industry entitled “Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report,” information concerning potential adverse experiences derived during planned contacts and active solicitation of information from patients should be

handled as safety information obtained from a postmarketing study. Section G of the previous and revised Form FDA 3500A contains a checkbox for “Study” which captures such information.

One comment requested that FDA include information on drug name, dose, frequency, route, dates of diagnosis for use, and event abated/reappeared after reintroduction on one line of Form FDA 3500 and Form FDA 3500A. FDA disagrees since these changes would decrease form clarity and would require costly and unnecessary computer and process revisions.

One comment noted that the MedWatch program needs to do the following: (1) Enhance the quality, utility, and clarity of information to be collected; (2) data entry accuracy needs to be improved; and (3) the public version of the adverse events database needs to be posted in a timely manner, and FDA needs to vigorously enforce mandatory reporting requirements. FDA acknowledges these comments regarding FDA programs and processes. However, the comment did not suggest specific changes to Form FDA 3500 or Form FDA 3500A.

In the final versions of Form FDA 3500 and Form FDA 3500A, there are some differences. FDA proposed adding two checkboxes to section B.1: “Product Use Error” and “Product Switch”. Since there is currently no requirement to report medication, device, or other regulated product errors, these boxes do not appear on the final version of Form FDA 3500A. However, “Product Use Error” will be included on the voluntary Form FDA 3500, as the agency has become aware that voluntary reporters who wish to submit medication and other product use errors to FDA are not certain that Form FDA 3500 can be used for this purpose. FDA encourages voluntary reporting of product use errors.

The “Product Switch” checkbox does not appear on the final Form FDA 3500A, however, a revised checkbox “Problem with different manufacturer of same medicine,” does appear on Form FDA 3500 to enable voluntary reporters to more clearly submit reports directly to FDA that involve adverse events or product problems related to brand-to-generic, generic-to-brand, one generic to another generic, or other therapy changes relating to the same active ingredient produced by different manufacturers.

FDA proposed reformatting changes in sections A and D of both forms to conserve space on the forms. These changes do not appear on the final Form FDA 3500A; however, section D

(Suspect Product(s)) of revised Form FDA 3500 is modified. FDA believes the collection of data in specific boxes for dose/amount, frequency, and route increases clarity and enhances the likelihood that these data would be obtained from consumers and healthcare professionals who voluntarily submit reports directly to FDA.

Several comments were received on new section C (Product Availability). Pharmaceutical manufacturers expressed concern that the practice of obtaining, storing, and analyzing returned products would significantly impact their working practice and goes beyond current regulations and guidances. FDA agrees with these comments and the “Product Availability” question has been returned to the “Suspect Medical Device” section of Form FDA 3500A. However, the revised voluntary Form FDA 3500 contains the new section C, to enable FDA to collect such information particularly for products that currently do not have mandatory adverse event reporting requirements, such as special nutritional products and cosmetics.

Dated: August 9, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 2005N–0218]

#### **Vision 2006—A Conversation With the American Public; Notice of Public Meetings on Specific Food and Drug Administration Issues; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meetings; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a series of public meetings entitled “Vision 2006—A Conversation With the American Public,” in three cities. This forum will be an open format in which consumers can interact directly with the agency’s leadership to discuss what is on the public’s mind. It will also be an opportunity for the agency to update the public on current agency programs, engage the public in discussion, and obtain consumer input on specific

issues. We may use the public input we receive to evaluate and to propose modifications, if necessary, to our programs and activities.

**DATES:** See table 1, section III, of the **SUPPLEMENTARY INFORMATION** section of this document for meeting dates and times. See section IV of this document for information on how to register, to speak at, or to attend a meeting. Written or electronic comments must be received by November 30, 2005.

**ADDRESSES:** See table 1, section III, of the **SUPPLEMENTARY INFORMATION** section of this document for meeting locations. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

*For information about this document:*

Philip L. Chao, Food and Drug Administration (HF-23), 5600 Fishers Lane, Rockville, MD 20857, 301-827-0587, FAX: 301-827-4774, e-mail:

[philip.chao@fda.hhs.gov](mailto:philip.chao@fda.hhs.gov).

*For information regarding*

registration: Isabelle Howes, Graduate School, U.S. Department of Agriculture, 490 L'Enfant Plaza, Promenade Level, suite 710, Washington, DC 20024, 202-314-4713, FAX: 202-479-6801, e-mail: [Isabelle\\_Howes@grad.usda.gov](mailto:Isabelle_Howes@grad.usda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Why Do We Want to Hold Public Meetings?**

New medical products have played a critical role in improving the lives of millions of Americans, providing much-needed treatments and cures for a wide range of illnesses. New advances in food technology and nutrition have enabled consumers to improve their health and well-being in countless ways. As we move forward in the 21st century, Americans are rightly concerned that advances in science should continue to translate into better products and technologies that can benefit their health.

FDA lies at a critical juncture to enable these kinds of advances in science, technology, and health. The agency is responsible for protecting and promoting the public health by ensuring the safety and effectiveness of most human and animal drugs; biological products such as vaccines, cellular therapies, and blood; medical devices;

tissues, and radiation-emitting products such as x-ray machines. We are also responsible for ensuring the safety and wholesomeness of food (including animal feed and dietary supplements) and cosmetics. Many Americans are rightly interested in FDA's programs, and the steps that the agency is taking to ensure that the promise of better science translates into longer lives with fewer problems from today's diseases. Consumers also want the opportunity to participate, in a meaningful way, in our work, whether we are discussing a complex scientific issue, proposing a regulation to address a particular problem, or implementing a new law.

We are holding these public meetings to help enhance this dialogue. This series of meetings will be an open forum in which consumers can interact directly with the agency's top leadership, including its leading scientists, to discuss what is on the public's mind.

We already provide similar opportunities for the public to engage in the agency's decisionmaking processes. We encourage people to take advantage of these regular opportunities to provide the agency with critical input into its programs. For example, the agency hosts frequent public meetings to discuss specific topics, reserves time during advisory committee meetings for public input, and invites the public to submit written or electronic comments on our rules. In 2004, we received more than 140,000 comments (including form letters) on rules, notices, and other matters. But the series of public meetings being announced in this document is a unique gathering of all of the agency's top leadership, including FDA Commissioner of Food and Drugs Lester Crawford, to provide direct feedback in an open forum on a broad range of issues of interest to the public.

Through the public meetings we are announcing in this document, we are also offering an opportunity for the public to hear more about, and to give us input on, specific programs or initiatives that we are currently pursuing to better protect and advance the public health. Public input will help us shape the agency's agenda for 2006 and beyond, as we commence our second century of serving the American public. Among some of the topics that we hope to discuss at the meetings are new opportunities to advance the safe use of medical products, increase the public health benefits of direct-to-consumer advertising, guarantee the safety and reliability of dietary supplements, and improve the science of drug development by lowering the cost of new medical products and

speeding access to better medical technologies through the agency's "Critical Path" initiative. We also hope to discuss our continuing efforts to increase public understanding of, and involvement in, the agency's scientific and regulatory processes—for example, through our advisory committee process and through improved, direct communication with consumers.

Through this open dialogue, the agency's leadership hopes to gain valuable insight from those who benefit from its regulatory efforts. FDA appreciates all of the consumer interest in its activities, and the agency's programs have benefited greatly from the feedback FDA receives from its many constituencies. To increase the transparency of our decisionmaking process, we are developing new, and expanding existing, communications channels to provide targeted information about new products to the public. We believe patients, healthcare professionals, and consumers will find the information useful in their individual treatment decisions. In an era when more and more of the products that people use are personalized to their individual needs, especially medical products and dietary choices, communicating the unique risks and benefits of individual products, and matching them to patients' individual needs, becomes paramount.

We want to ensure the information we provide and new efforts we are undertaking provide maximum value to consumers. Among the many questions we would like the public to consider are the following:

- What information do you expect to receive from FDA regarding the benefits and risks of new food and medical products?
- Where do you currently get information about these products, and how beneficial is this information in helping to inform the decisions you make?
- What additional information, if any, do you believe should be provided to enable you to discuss with your physician or other health care provider the benefits and risks of products for a health condition you have or think you might have?
- What additional steps can FDA take to improve its communication with consumers and build on your confidence in its activities and its mission?

**II. How Should You Send Comments on the Issues?**

If you would like to submit comments on any of the issues discussed in this document, 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 should 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. To ensure consideration of your comments, we must receive any written or electronic comments by November 30, 2005.

**III. Where and When Will the Meetings Occur?**

We will hold public meetings in three cities to discuss the issues described earlier in this document. The meetings are scheduled from 10 a.m. to 4 p.m.

The meeting dates, times, and locations are as follows:

TABLE 1.—MEETING DATES, TIMES, AND LOCATIONS

Location	Meeting Site Address	Meeting Date and Time
Boston, MA	Boston Marriott Cambridge, 2 Cambridge Center (Broadway and 3d St.), Cambridge, MA 02142	November 2, 2005, 10 a.m. to 4 p.m.
Miami, FL	Intercontinental West Miami, 2505 Northwest 87th Ave., Miami, FL 33172	September 13, 2005, 10 a.m. to 4 p.m.
Phoenix, AZ	Phoenix Airport Marriott, 1101 North 44th St., Phoenix, AZ 85008	November 30, 2005, 10 a.m. to 4 p.m.

**IV. Do You Have to Register to Make a Presentation at or to Attend a Meeting?**

If you wish to make a presentation at or to attend any meeting, please register online at <http://www.grad.usda.gov/vision> at least 5 business days before the appropriate meeting date. The online registration form will instruct you as to the information you should provide (such as name, address, telephone number, electronic mail address, topic(s) of interest, whether you wish to make a presentation, and which meeting you wish to attend). We also will accept walk-in registrations on the meeting dates. However, space is limited, and we will close registration at each site when maximum seating capacity for that site is reached (approximately 150 people per location).

We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations will depend on the number of people who wish to speak on a given topic, and the meeting schedule at each location. Similarly, the time allotted to each topic may vary depending on the expressed interests of persons registering for a particular meeting. To obtain updates on the meetings, please visit <http://www.fda.gov/oc/initiatives/vision2006.html>. Additionally, regardless of whether you wish to make a presentation or simply attend a meeting, if you need any special accommodations (such as wheelchair access or a sign language interpreter), please notify Isabelle Howes (see **FOR**

**FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

**V. Will Meeting Transcripts Be Available?**

We will prepare transcripts of each meeting. You may request a copy of a meeting transcript by writing to our Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857. We anticipate that transcripts will be available approximately 30 business days after the public meetings at a cost of 10 cents per page. The transcripts will also be available for public examination at the Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 11, 2005.  
**Jeffrey Shuren**,  
*Assistant Commissioner for Policy.*  
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**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 (OMB), 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: Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy) (OMB No. 0915-0047)—Extension**

The regulations for the Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program contain a number of reporting and recordkeeping requirements for schools and loan applicants. The requirements are essential for assuring that borrowers are aware of rights and responsibilities that schools know the history and status of each loan account that schools pursue aggressive collection efforts to reduce default rates, and that they maintain adequate records for audit and assessment purposes. Schools are free to use improved information technology to manage the information required by the regulations.

The burden estimates are as follows:

**RECORDKEEPING REQUIREMENTS**

Regulatory/section requirements	Number of recordkeepers	Hours per year	Total burden hours
HPSL Program: 57.206(b)(2), Documentation of Cost of Attendance .....	547	1.17	640