manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after February 8, 2008, or is not currently marketed but is subsequently manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after February 8, 2008.

However, for currently marketed and listed unapproved colchicine for injection products, the agency intends to exercise its enforcement discretion after February 8, 2008, as identified elsewhere in this document. FDA intends to initiate enforcement action against any currently marketed and listed colchicine for injection product that is manufactured on or after March 10, 2008, or that is shipped on or after August 6, 2008[4]. Further, FDA intends to take enforcement action against any person who manufactures or ships such products after the dates set forth previously. Any person who submits an NDA for a colchicine for injection product but has not received approval must comply with this notice.

The agency, however, does not intend to exercise its enforcement discretion as outlined previously if the following apply: (1) A manufacturer or distributor of an unapproved injectable colchicine product covered by this notice is violating other provisions of the act, including but not limited to, violations related to FDA's current good manufacturing practices, adverse drug event reporting, misbranding, or other violations, or (2) it appears that a firm, in response to this notice, increases its manufacture or interstate shipment of injectable colchicine drug products above its usual volume during these periods.

Nothing in this notice, including FDA's intent to exercise its enforcement discretion, alters any person's liability or obligations in any other enforcement action, or precludes the agency from initiating or proceeding with enforcement action in connection with any other alleged violation of the act, whether or not related to an unapproved drug product covered by this notice.

[4]If FDA finds it necessary to take enforcement action against a product covered by this notice, the agency may take action relating to all of the defendent's other violations of the act at the same time. For example, if a firm continues to manufacture or market a product covered by this notice after the applicable enforement date has passed, to preserve limited agency resources, FDA may take enforcement action relating to all of the firm's unapproved drugs that require applications at the same time (see e.g. *United States v. Sage Phamaceuticals*, 210 F3d 475, 479-480 (5th Cir. 2000) (permitting the agency to combine all violations of the act in one proceeding, rather than taking action against multiple violations of the act in ''piecemeal fashion'')).

Similarly, a person who is or becomes enjoined from marketing unapproved drugs may not resume marketing of unapproved injectable colchicine products based on FDA's exercise of enforcement discretion as set forth in this notice.

Drug manufacturers and distributors should be aware that the agency is exercising its enforcement discretion as described previously only in regard to colchicine for injection products that are marketed under an NDC number listed with the agency before February 6, 2008. As previously stated, unapproved colchicine for injection products that are currently marketed and not listed with the agency on the date of this notice must, as of the effective date of this notice, have approved applications prior to their shipment in interstate commerce. Moreover, any person or firm that submits an NDA but has yet to receive approval for such products is still responsible for full compliance with this notice.

C. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the act. Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including NDC number(s), and stating that the product(s) has (have) been discontinued and will not be marketed again without FDA approval. The letter should be sent to Jennifer Devine, (see **ADDRESSES**). Firms should also update the listing of their products under section 510(j) of the act to reflect discontinuation of unapproved colchicine for injection products. FDA plans to rely on its existing records, the results of a subsequent inspection, or other available information when it initiates enforcement action.

This notice is issued under the act (sections 502 (21 U.S.C. 352)) and 505 and under authority delegated to the Deputy Commissioner for Policy under section 1410.10 of the FDA Staff Manual Guide.

Dated: January 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 08–564 Filed 2–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Risk Communication Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communication Advisory Committee

General Function of the Committee: To provide advice and recommendations to the agency on effective risk communication.

Date and Time: The meeting will be held on February 28, 2008, from 8 a.m. to 5 p.m. and February 29, 2008, from 8 a.m. to 4 p.m.

Location: Washington DC North/ Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877, Salons A, B, C, and D.

Contact Person: Lee L. Zwanziger, Office of the Commissioner, Office of Planning (HFP–60), Food and Drug Administration, 5600 Fishers Lane, rm.15–22, Rockville, MD, 20857, 301–827–2895, Fax: 301–827–5340, Food and Drug Administration, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732112560. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that affect a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 28, 2008, the committee will meet for the first time, for presentations and discussion of the relation of FDA's risk communication programs and FDA's responsibilities. On February 29, 2008, the meeting will continue with presentations and discussion of FDA's proposed template for press releases announcing product recalls with a view to incorporating best practices of risk communication.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 20, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on February 28th and 11:15 to 12:15 on February 29th. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 11, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 12, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lee L. Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 3, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. 08–588 Filed 2–5–08; 3:58 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Inspector General

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part A (Office of the Secretary), chapter AF of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) to reflect title changes and responsibilities within the Office of Inspector General's (OIG) Office of Investigations (OI). The statement of organization, functions, and delegations of authority conforms to and carries out the statutory requirements for operating OIG. These organizational changes are primarily to balance investigative operations and investigative support functions within OI, more clearly delineate responsibilities for the activities within this office, and facilitate the most efficient and effective health care fraud investigations. Chapter AF was last amended on December 21, 2006 (71 FR 76676).

As amended, sections AFJ.00, AFJ.10, and AFJ.20 of Chapter AF now read as follows:

* * * * *

Section AFJ.00, Office of Investigations—Mission

The Office of Investigations (OI) is responsible for conducting and coordinating investigative activities related to fraud, waste, abuse, and mismanagement in HHS programs and operations, including wrongdoing by applicants, grantees, and contractors, or by HHS employees in the performance of their official duties. The office serves as OIG liaison to Department of Justice on all matters relating to investigations of HHS programs and personnel, and reports to the Attorney General when OIG has reasonable grounds to believe Federal criminal law has been violated. The office serves as a liaison to CMS, State licensing boards, and other outside organizations and entities with regard to exclusion, compliance, and enforcement activities. OI works with other investigative agencies and organizations on special projects and assignments. In support of its mission, the office carries out and maintains an internal quality assurance system. The system includes quality assessment studies and quality control reviews of OI processes and products to ensure that policies and procedures are followed effectively, and are functioning as intended.

Section AFJ.10, Office of Investigations—Organization

This office is comprised of the following components:

A. Immediate Office
B. Investigations Division 1
C. Investigations Division 2

Section AFJ.20, Office of Investigations—Functions

A. Immediate Office of the Deputy Inspector General for Investigations

This office is directed by the Deputy Inspector General for Investigations (DIGI), who is responsible for the functions designated in the law for the position Assistant Inspector General for Investigations. The DIGI supervises the Assistant Inspector General for Investigations Division 1, the Assistant Inspector General for Investigations Division 2, and the Special Advisor who heads the offices described below.

The DIGI is responsible to the Inspector General for carrying out the investigative mission of OIG and for providing and leading general supervision to the OIG investigative component. The Immediate Office provides broad guidance and instruction to staff and serves as the focal point for interaction within OIG. The Immediate Office handles all investigative and management advisory services for the DIGI, ensuring that the DIGI is briefed on all complex, sensitive, and precedent setting program and administrative issues that may significantly impact on OI management and the investigative program nationwide. The Special Advisor to the DIGI will supervise the Special Investigations Unit (SIU) Director and a group of inspectors. The SIU will conduct investigations concerning alleged electronic and computer-related violations, as well as conduct sensitive and complex investigations concerning alleged misconduct by OIG and some Department employees. Separately, the inspectors who report directly to the Special Advisor will conduct the most sensitive investigations involving senior officials, political appointees, national security issues, and subjects of high media interest. Additionally, those inspectors will coordinate special projects as assigned by the Special Advisor and investigations involving Congress and top echelon Executive Branch Officials.