100 milligram (mg) tablets, by Boehringer Ingelheim Pharmaceuticals, Inc., for the proposed indication of the treatment of hypoactive sexual desire disorder in premenopausal women.

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/AdvisoryCommittees/Calendar/default.htm. 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 June 3, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 May 25, 2010. 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 May 26, 2010.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing accommodations for persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.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: April 12, 2010.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council will meet on May 11–12 at SAMHSA, Rockville, Maryland. The meeting is open to the public.

The SAMHSA National Advisory Council was established to advise the Secretary, Department of Health and Human Services (HHS), and the Administrator, SAMHSA, to reduce the impact of substance abuse and mental illnesses in American communities. The Agenda will include a report from the new SAMHSA Administrator and presentations and discussions related to SAMHSA’s 10 strategic initiatives that will focus the Agency’s work on improving lives and capitalizing on emerging opportunities that advance and protect the Nation’s health.

Attendance by the public will be limited to space available. Public comments are welcome. The meeting can also be accessed via webcast. To obtain the call-in numbers and access codes, to submit written or brief oral comments, or to request special accommodations for persons with disabilities, please register on-line at https://nac.samhsa.gov/Registration/meetingsRegistration.aspx. You may also communicate with the SAMHSA National Advisory Council Designated Federal Officer, Ms. Toian Vaughn (see contact information below).

Substantive program information and a roster of Council members may be obtained either by accessing the SAMHSA Committee Web site, https://nac.samhsa.gov/NACouncil/index.aspx or by contacting Ms. Vaughn. The transcript for the meeting will be available on the SAMHSA Committee Web site within three weeks after the meeting.

Committee Name: SAMHSA National Advisory Council.

Date/Time/Type: Tuesday, May 11, 2010, from 9 a.m. to 6 p.m.; OPEN. Wednesday, May 12, 2010, from 9 a.m. to 3 p.m.; OPEN.

Place: Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Rd., Sugarloaf and Seneca Conference Rooms, Rockville, Maryland 20857.

Contact: Toian Vaughn, M.S.W., designated Federal Official, SAMHSA National Advisory Council and SAMHSA Committee Management Officer, 1 Choke Cherry Road, Room 8–1089, Rockville, Maryland 20857; Telephone: (240) 276–2307; FAX: (240) 276–2220 and E-mail: toian.vaughn@samhsa.hhs.gov.

Toian Vaughn,
Committee Management Officer, Substance Abuse and Mental Health Services Administration.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Tobacco Product Constituents Subcommittee of the Tobacco Products Scientific 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: Tobacco Product Constituents Subcommittee of the Tobacco Products Scientific Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on June 8, 2010, from 8:30 a.m. to 5 p.m. and on June 9, 2010, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel phone number is 301–948–8900.

Contact Person: Karen Templeton-Somers, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–267–1373 (choose Option 4), e-mail: TPSAC@fda.hhs.gov or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code: 8732110002. Please call the Information
Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact 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 June 8 and 9, 2010, the subcommittee will receive presentations and discuss the development of a list of harmful or potentially harmful constituents, including smoke constituents, in tobacco products. Topics for discussion will include the criteria for selection of the constituents, developing a proposed list of harmful or potentially harmful constituents, the rationale for including each constituent, and the acceptable analytical methods for assessing the quantity of each constituent. A second meeting of this subcommittee, to continue these discussions as necessary and to include ancillary and normalization standards for the constituents, will be scheduled for the summer of 2010.

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/AdvisoryCommittees/Calendar/default.htm. 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 May 28, 2010. Oral presentations from the public will be scheduled between approximately 2:45 p.m. and 3:45 p.m. on June 8, 2010. 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 May 20, 2010. 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 May 21, 2010.

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 Karen Templeton-Somers 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

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

Dated: April 21, 2010.

Jill Hartzler Warner, Acting Associate Commissioner for Special Medical Programs.

[FDR Doc. 2010–9662 Filed 4–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–153–A]

Request for the Technical Review of 22 Draft Skin Notation Assignments and Skin Notation Profiles

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public comment period.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) is conducting a public review of the draft skin notations and support technical documents entitled “Skin Notations Profiles, for 22 chemicals.” NIOSH is requesting technical reviews of the draft Skin Notation Profiles. To facilitate the review of these documents, NIOSH requests that the following questions be taken into consideration:

1. Does this document clearly outline the systemic health hazards associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?

2. If the SYS or SYS (FATAL) notations are assigned, is the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (e.g., insufficient data, no identified health hazard)?

3. Does this document clearly outline the direct (localized) health hazards associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?

4. If the DIR, DIR (IRR), or DIR (COR) notations are assigned, is the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (e.g., insufficient data, no identified health hazard)?

5. Does this document clearly outline the immune-mediated responses (allergic response) health hazards associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?

6. If the SEN notation is assigned, is the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (e.g., insufficient data, no identified health hazard)?

7. If the ID(SK) or SK were assigned, is the rationale and logic outlined within the document?

8. Are the conclusions supported by the data?

9. Are the tables clear and appropriate?

10. Is the document organized appropriately? If not, what improvements are needed?

11. Is the language of the manuscript acceptable as written? If not, what improvements are needed?

12. Are you aware of any scientific data reported in governmental publications, databases, peer-reviewed journals, or other sources that should be included within this document?

13. What is your final recommendation for this manuscript?

Public Comment Period: Comments must be received by June 11, 2010.

ADDRESSES: You may submit comments, identified by docket number NIOSH–153–A, by any of the following methods:

- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226.