or in combination with other active ingredients, that are not currently marketed products on the effective date of this notice must, as of this date, have approved applications prior to their shipment in interstate commerce. However, for unapproved timed-release guaifenesin products that are currently marketed as of the date of this notice (i.e., timed-release guaifenesin products that are not approved but have an NDC number that is listed with the agency on the effective date of this notice), the agency intends to exercise its enforcement discretion to permit the products marketed with those NDC numbers a period of continued marketing after May 29, 2007 as follows. FDA does not intend to initiate enforcement actions against firms that are manufacturing currently marketed products unless those firms are still manufacturing the products on or after August 27, 2007. Further, FDA does not intend to initiate enforcement actions related to the shipment in interstate commerce of currently marketed products made by such firms unless they are still being shipped on or after November 26, 2007.[2] The agency, however, does not intend to exercise its enforcement discretion as outlined in this paragraph if: (1) A manufacturer or distributor of an unapproved product covered by this notice is violating other provisions of the act or (2) it appears that a firm, in response to this notice, increases its manufacture or interstate shipment of drug products covered by this notice above its usual volume during these periods.

Drug manufacturers and distributors should be aware that the agency is exercising its enforcement discretion as described previously only in regard to timed-release drug products containing guaifenesin that are marketed under an NDC number listed with the agency on the effective date of this notice. Such unapproved drug products that are not currently marketed and listed with the agency on the effective date of this notice must, as of the effective date of this notice, have approved applications prior to their shipment in interstate commerce. Moreover, submission of an application does not excuse timely compliance with this notice.

[2] If a firm continues to manufacture or market a product covered by this notice after the applicable enforcement 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 Pharmaceuticals*, 210 F.3d 475, 479–480 (5th Cir. 2000) (permitting the agency to combine all violations of the act in one proceeding, rather than taking action against a firm with multiple violations of the act in ''piecemeal fashion'')).

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 its NDC number(s), and stating that the product(s) has (have) been discontinued and will not be marketed again without FDA approval, to Sakineh Walther (see **ADDRESSES**). Firms should also update the listing of their products under section 510(j) of the act to reflect discontinuation of unapproved timed-release products containing guaifenesin. FDA plans to rely on its existing records, the results of a subsequent inspection, or other available information when it initiates enforcement action.

D. Reformulated Products

In addition to discontinuing the manufacturing of products covered by this notice, FDA cautions firms against reformulating their products into guaifenesin-free unapproved new drugs that are marketed under the same name or substantially the same name (including a new name that contains the old name). In the Marketed Unapproved Drugs CPG, FDA states that it intends to give higher priority to enforcement actions involving unapproved drugs that are reformulated to evade an FDA enforcement action. In addition, reformulated products marketed under a name previously identified with a different active ingredient or combination of active ingredients have the potential to confuse health care practitioners and harm patients. Depending on the circumstances, these products may be considered misbranded under section 502(a) or (i) of the act (21 U.S.C. 352(a) and (i)).

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

Dated: May 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10266 Filed 5–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0204]

Joint Meeting of the Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees: Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

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

Date and Time: The meeting will be held on July 31, 2007, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments*. Select ''2007— Efficacy and Safety of TYSABRI (natalizumab) for Patients With Moderately to Severely Active Crohn's Disease'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. Comments received on or before July 24, 2007, will be provided to the committee before the meeting.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Victoria Ferretti-Aceto, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Victoria.FerrettiAceto@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), codes 301–451–2538 and 301–451–2535. 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: The committee will discuss TYSABRI (natalizumab) biologic license application (BLA) 125104/33, Biogen Idec, Inc., for the proposed indication of inducing and maintaining sustained response and remission, and eliminating corticosteroid use in patients with moderately to severely active Crohn's disease with inflammation, as evidenced by elevated C-reactive protein level or another objective marker. The committee will discuss the risks (including progressive multifocal leukoencephalopathy) associated with TYSABRI (natalizumab) administration, its efficacy in the treatment of moderate to severe Crohn's disease, and proposed risk management plan(s).

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 2007 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 July 18, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2:30 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 July 10, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonable 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 July 11, 2007.

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 Victoria Ferretti-Aceto at least 7 days in advance of the meeting.

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

Dated: May 22, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–10270 Filed 5–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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 July 17, 2007, from 8 a.m. to 5 p.m.

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

Contact Person: Ronald P. Jean, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 240–276–3676, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512521. 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: The committee will discuss, make recommendations, and vote on a premarket approval application for the Bryan Total Cervical Disc Prosthesis, sponsored by Medtronic Sofamor Danek, Inc. This device is indicated in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C3–C7. DDD is defined as any combination of the following: Disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy.

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 2007 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 July 3, 2007. Oral presentations from the public will be scheduled for 30 minutes at the beginning of the committee deliberations and for 30 minutes near the end of the deliberations, 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 June 25, 2007. 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 June 26, 2007.