CP1) under 21 CFR 10.30 to FDA. The petition requested that the agency determine whether metformin HCl tablets, 625- and 750-mg were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and, under § 314.161, has determined that Bristol-Myers Squibb's decision not to market metformin HCl 625- and 750-mg tablets was not due to concerns about safety or effectiveness of the product. Accordingly, the agency will maintain metformin HCl 625- and 750-mg tablets in the ''Discontinued Drug Product List'' section of the Orange Book.

The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to metformin HCl 625- and 750-mg tablets may be approved by the agency.

Dated: June 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–15442 Filed 6–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers 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: Biological Response Modifiers 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 13, 2001, 8:30 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Gail Dapolito or Rosanna L. Harvey (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will meet to: (1) Discuss responses to the March 6, 2000, FDA gene therapy letter (http://www.fda.gov/cber/letters.htm) relating to adenovirus vector titer measurements and replication competent adenovirus levels reporting, and (2) hear updates on the NIH final action on serious adverse reporting.

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 by July 6, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 6, 2001, 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.

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

Dated: June 12, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–15443 Filed 6–19–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1075]

Public Health Impact of Vibrio Parahaemolyticus in Raw Molluscan Shellfish; Draft Risk Assessment Document; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until July 18, 2001, the comment period on its draft risk assessment on the relationship between *Vibrio parahaemolyticus* in raw molluscan shellfish and human health (66 FR 5517, January 19, 2001). Interested persons were initially given until March 20, 2001, with an extension to May 21, 2001 (66 FR 13546, March 6, 2001), to comment on the draft risk assessment. This reopening of the comment period is in response to a request from the National Fisheries Institute (NFI) on behalf of the Gulf Oyster Industry Council, the Pacific Coast Shellfish Growers Association, and the Molluscan Shellfish Institute. The agency does not anticipate further extensions of the comment period for this draft risk assessment.

DATES: Submit written comments by July 18, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of comments are to be submitted, except that individuals may submit one copy. Comments must be identified with the docket number found in brackets in the heading of this document. Received comments may be reviewed at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–260–3984, FAX 202–260–9653, e-mail: sdennis@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 19, 2001 (66 FR 5517), FDA announced the availability of a draft risk assessment on the relationship between *Vibrio parahaemolyticus* in raw molluscan shellfish and human health. Comments were sought on the technical aspects of the draft risk assessment in the following areas: (1) The assumptions made, (2) the modeling technique, (3) the data used, and (4) the transparency of the draft risk assessment document. Interested persons were given until March 20, 2001, to comment on the draft risk assessment. In the **Federal Register** of March 6, 2001, FDA extended the comment period to May 21, 2001 (66 FR 13546), because a public meeting to receive comments on the document was scheduled for March 20, 2001 (March 6, 2001, 66 FR 13544), the same day the comment period closed. The NFI, on behalf of the Gulf Oyster Industry Council, the Pacific Coast Shellfish Growers Association, and the Molluscan Shellfish Institute, has requested a second extension of the comment period to allow additional time to review, analyze, and constructively respond to the draft risk assessment. The extended comment period closed on May 21, 2001. FDA, in response to the NFI request, is