comprised of a subset of user facilities is called the Medical Product Surveillance Network (MedSuN). The 60-day **Federal Register** notice announced that two FDA Centers, the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) would be participating in this project. However, CBER will no longer participate in this project; CDRH will be the sole participant. Data collected from the pilot will aid FDA in fulfilling its mission to monitor the safety and effectiveness of marketed medical devices as they are used in clinical settings and to determine what aspects of the pilot program should be implemented in the national program. The current FDA universal user-facility reporting system remains in place during the piloting of the new program, and will remain until FDA implements the new MedSuN national system by regulation.

An electronic format of the medical device related sections of the mandatory MedWATCH form (form 3500A; OMB Control number 0910–0291) will be accessible to the participating medical device user facilities. The facilities participating in the collection of medical device-related adverse events will use this electronic format in reporting to FDA. The electronic format will include some additional items that are not on the 3500A form. These will be voluntary for participants to complete, such as hospital profile information and several questions related to the use of medical devices.

Participation in this pilot will be voluntary and will initially include 25 hospitals that will respond to the medical device questions. It is anticipated that during this pilot the number of participants will increase to approximately 250 facilities reporting medical device problems. The electronic version will take approximately 45 minutes, or less, to complete.

In the **Federal Register** of February 8, 2001 (66 FR 9580), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency perResponse	Total Annual Responses	Hoursper Response	Total Hours
Medical devices: 83	15	1,245	.75	934
Total				934

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents for medical devices was determined by the average number of respondents given that 25 facilities will be enrolled in the first year, up to 100 the second year, and up to 250 the third year. Eighty-three is the average of the final complement of 250 facilities. The annual frequency of response is based on FDA's experience with its mandatory and voluntary reporting systems.

Dated: June 14, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–15440 Filed 6–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1496]

Determination That Metformin Hydrochloride Tablets, 625 and 750 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that metformin hydrochloride (HCl) tablets (Glucophage), 625 and 750 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for metformin HCl 625- and 750-mg tablets.

FOR FURTHER INFORMATION CONTACT: Paul C. Varki, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Metformin HCl 625- and 750-mg tablets are the subject of NDA 20–357. When first approved, the NDA provided for 500- and 850-mg tablets. On July 8, 1998, Bristol-Myers Squibb Co. submitted a supplemental NDA to market the 625-, 750-, and 1000-mg tablets. FDA approved this supplement on November 5, 1998. On November 11, 1998, Bristol-Myers Squibb notified FDA that it would not market the 750-mg strength tablet. The 625-mg strength tablet has not been marketed either.

On August 31, 2000, Lachman Consultant Services, Inc., submitted a citizen petition (Docket No. 00P–1496/

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]

BILLING CODE 4160–01–S

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