implementation and its monitoring over time; the use of these resources to leverage additional resources for plan implementation; the plans to institutionalize specific interventions; specific objectives that are realistic, measurable and time phased; clear definition of both process and outcome measures for the evaluation of implementation activities.

6. Management and Staffing for Intervention Activities (15 points)

The current functioning of asthma staff (program and surveillance) within the health agency; the description of staff to be hired or contracts to be developed; the link of staff to program objectives; the continued role of the statewide partnership group. Assurance that key personnel will attend scheduled grantee meetings and CDC-sponsored national asthma conferences, and that the applicant agrees to share innovations, information, data and materials.

7. Budget (Not scored)

The extent to which the budget is reasonable, adequately justified and consistent with the intended use of the cooperative agreement funds.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Annual progress reports;
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 2 of the announcement in the application kit.

AR–7 Executive Order 12372 Review
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act, [42 U.S.C. section 241 and 247b], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where to Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address http://www.cdc.gov Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To obtain business management technical assistance, contact: Sonia Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: (770) 488–2724, Email address: svp1@cdc.gov.

For program technical assistance, contact: Leslie P. Boss, Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, Mailstop E–17, 1600 Clifton Rd., NE, Atlanta, GA 30333, Telephone number: (404) 498–1002, Email address: LBoss@cdc.gov.

Dated: June 14, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–15476 Filed 6–19–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0051]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Adverse Event Pilot Program for Medical Devices and Blood Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written or electronic comments on the collection of information by July 20, 2001.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Adverse Event Pilot Program for Medical Devices and Blood Products

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions and to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 213 of the FDA Modernization Act of 1997 (FDAMA) amended section 519(b) of the act relating to mandatory reporting by user facilities of deaths and serious injuries and serious illnesses associated with the use of medical devices. This amendment required FDA to, by regulation, replace universal user-facility reporting with a system that is limited to a '' * * * subset of user facilities that constitutes a representative profile of user reports'' for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the act.

FDA is the Federal agency charged with the responsibility for ensuring that marketed medical products are safe and effective. To carry out its responsibilities, the agency needs to be informed whenever an adverse event or product problem occurs. Only if FDA is provided with such information will it be able to evaluate the risk, if any, associated with the product and take whatever action is necessary to reduce or eliminate the public's exposure to this risk. Data collected from user facilities about problems with medical devices assist FDA to carry out that mission as it pertains to medical devices. Prior to implementing the regulation to change from universal user-facility reporting to reporting by a subset of user facilities, FDA is planning to conduct a pilot program to evaluate various aspects of the new program. The new user-facility program that will be

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]

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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/