review, institutions that might otherwise be subject to the RCR policy are under no obligation to implement the policy unless further public notice is issued in the **Federal Register**. Any future PHS action taken to implement the RCR policy would provide extended implementation time frames that take into consideration this suspension.

FOR FURTHER INFORMATION CONTACT: Barbara Bullman, J.D., Senior Program Analyst, Division of Education and Integrity, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5300.

Chris B. Pascal, J.D.,

Director, Office of Research Integrity.

[FR Doc. 01–4226 Filed 2–20–01; 8:45 am]

BILLING CODE 4150–31–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: TANF High Performance Bonus Report, Assessment of Medicaid and SCHIP Enrollment.

OMB No.: New Collection.

Description: Public Law 104–93 (PRWORA) established the Temporary Assistance for Needy Families (TANF) Program. It also included provisions for rewarding States that attain the highest levels of success in achieving the legislative goals of that program. The purpose of this collection is to obtain data upon which to base the computation for measuring State performance in meeting those goals by providing Medicaid and SCHIP work supports. DHHS will use the information to allocate the Medicaid/SCHIP portion of the bonus grant funds appropriated under the law and implemented by 45 CFR part 270 published on August 30, 2000. States will not be required to submit this information unless they elect to compete in a Medicaid/SCHIP measure for the TANF High Performance Bonus awards in Federal fiscal years 2002 or 2003, or any subsequent Federal fiscal year for which Congress authorizes and appropriates bonus funds.

Respondents: Respondents may include any of the 50 States, the District of Columbia, and the U.S. Territories of Guam, Puerto Rico, and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	No. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours
TANF high performance bonus report, assessment of Medicaid and SCHIP enrollment among individuals after leaving TANF assistance	54	2	40	4,320
Estimated total annual burden hours				4,320

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 14, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–4188 Filed 2–20–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Allergenic Products 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 March 5, 2001, 8:30 a.m. to 5 p.m.

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

Contact: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (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 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 5, 2001, the committee will hear updates on: (1) The Laboratory of Immunobiochemistry personnel, (2) lot release statistics, (3) new guidance documents, (4) research and standardization programs, and (5) a compliance report. The committee will discuss whether master seed stocks of mold strains used for allergenic extracts should be rederived to reduce a theoretical risk of transmissible spongiform encephalopathy transmission. The committee will also discuss the statistical power of clinical studies used to assess bioequivalence as it applies to allergen extract studies. In the afternoon, the committee will discuss particulates that appear in allergen extracts and the effect of these particulates on the safety and efficacy on these products. In closed session, the committee will receive a report on the status of an investigational new drug application and product license application supplement.

Procedure: On March 5, 2001, from 8:30 a.m. to 3:30 p.m., the meeting is open to the

public. 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 February 17, 2001. Oral presentations from the public will be scheduled between approximately 11:10 a.m. and 11:40 a.m., and between approximately 2:40 p.m. and 3:10 p.m. on March 5, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 21, 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.

Closed Committee Deliberations: On March 5, 2001, from approximately 3:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion will be closed to permit discussion of these materials.

FDA regrets that it was unable to publish this notice 15 days prior to the March 5, 2001, Allergenic Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Allergenic Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: February 14, 2001.

Bonnie H. Malkin,

Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01–4230 Filed 2–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0057]

Determination That Bethanechol Chloride Injection and Tablets 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 bethanechol chloride 5 milligrams (mg) per milliliter (mL) injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets, all formerly marketed by Merck & Co., Inc. (Merck), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDA's) for bethanechol chloride drug products, and it will also allow FDA to continue to approve ANDA's for bethanechol chloride drug products.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 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 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. Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 to which the ANDA refers.

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). Under § 314.161(a)(2) (21 CFR 314.161(a)(2)) the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDA's that refer to the drug that was withdrawn are approved. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will begin proceedings to withdraw approval of the ANDA's that refer to the drug that was withdrawn from sale.

FDA has received a letter, dated April 7, 2000, from Merck, holder of NDA 6–536 for bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets, stating that Merck has withdrawn those products from sale. Danbury Pharmacal, Inc., Roberts Laboratories, Inc., Glenwood, Inc., and Sidmak Laboratories, Inc. (Sidmak), all hold approved ANDA's that refer to one or more of Merck's bethanechol chloride drug products. Merck sold its bethanechol chloride drug products under the trade name of Urecholine. In their April 7, 2000, letter, Merck also informed FDA that Merck has assigned the trademark Urecholine to Sidmak for use in the sale of Sidmak's bethanechol chloride drug products.

FDA has reviewed its records and, under § 314.161, has determined that bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will list Merck's bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. The approval status of the ANDA's that refer to bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets is unaffected. ANDA's for bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets may be approved by the agency.

Dated: February 14, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–4229 Filed 2–20–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–9044]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration