that FDA will not consider re-proposing withdrawal proceedings in the future, if necessary. FDA has not ruled out the prospect of future regulatory action, either with respect to the antimicrobial new animal drugs covered by the 1977 NOOHs or any others. However, for now, FDA's efforts will focus on promoting voluntary reform and the judicious use of antimicrobials in the interest of best using the agency's overall resources to protect the public health. Importantly, this strategy leaves open the possibility of pursuing withdrawal proceedings at a later time if FDA's proposed strategy does not yield satisfactory results.

As indicated previously, as part of the withdrawal of the two 1977 NOOHs, the Agency will close their corresponding dockets. However, we encourage interested persons to submit comments to the docket established in connection with draft GFI #209. The docket number associated with draft GFI #209 is FDA–2010–D–0094.

IV. Penicillin and Tetracycline Uses in Animal Feed

FDA is withdrawing the 1977 NOOHs, and the related companion proposed rules, because: (1) FDA is engaging in other ongoing regulatory strategies developed since the publication of the 1977 NOOHs with respect to addressing microbial food safety issues; (2) FDA would update the NOOHs to reflect current data, information, and policies if, in the future, it decides to move forward with withdrawal of the approved uses of the new animal drugs described in the NOOHs; and (3) FDA would need to prioritize any withdrawal proceedings (for example, take into account which withdrawal(s) would likely have the most significant impact on the public health) if, in the future, it decides to seek withdrawal of the approved uses of any new animal drug or class of drugs.

V. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday (except on Federal holidays). We have verified all Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**

1. 42 FR 43772 (August 30, 1977).
2. 42 FR 56264 (October 21, 1977).
3. 42 FR 43770 (August 30, 1977).
4. 42 FR 56254 (October 21, 1977).
5. Draft GFI #209, ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,'' June 28, 2010; *http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf.*
6. 37 FR 2444 (February 1, 1972).
7. 38 FR 9811 (April 20, 1973).
8. 21 CFR 135.109 (revised as of April 1, 1974).
9. 21 CFR 558.15 (revised as of April 1, 1975).
10. H. Rept. 95–1290, ''Agriculture, Rural Development and Related Agencies Appropriation Bill, 1979,'' June 13, 1978.
11. H. Rept. 96–1095, ''Agriculture, Rural Development and Related Agencies Appropriation Bill, 1981,'' June 17, 1980.
12. S. Rept. 97–248, ''Agriculture, Rural Development and Related Agencies Appropriation Bill, 1982,'' October 23 (legislative day, October 14), 1981.
13. National Academy of Sciences/National Research Council, ''The Effects on Human Health of Subtherapeutic Uses of Antimicrobials in Animal Feeds,'' 1980, pp. 53–54.
14. 1984 Seattle-King County Study: ''Surveillance of the Flow of Salmonella and Campylobacter in a Community.''
15. National Academy of Sciences/Institute of Medicine, ''Human Health Risks With the Subtherapeutic Use of Penicillin or Tetracyclines in Animal Feed,'' 1988.
16. 68 FR 47272, 47275 (August 8, 2003).
17. 1997 World Health Organization (WHO) Report, '' The Medical Impact of Antimicrobial Use in Food Animals,'' *http://whqlibdoc.who.int/hq/1997/WHO_EMC_ZOO_97.4.pdf*
18. 1999 National Research Council (NRC) Report: ''The Use of Drugs in Food Animals–Benefits and Risks.''
19. A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals, *http://www/fda/gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm126607.htm.*
20. Final Guidance for Industry #152, ''Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern,'' October 23, 2003.
21. 75 FR 15387 (March 29, 2010).
22. *http://www/fda/gov/AnimalVeterinarySafetyHealth/AntimicrobialResistance/NationalAntimmicrobialResistanceMonitoringSystem/default.htm.*
23. 41 FR 8282 (February 25, 1976).

Dated: December 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32775 Filed 12–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0411]

Bristol-Myers Squibb Co. et al.; Withdrawal of Approval of 70 New Drug Applications and 97 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 8, 2011 (76 FR 33310). The document announced the withdrawal of approval of 70 new drug applications (NDAs) and 97 abbreviated new drug applications (ANDAs) from multiple applicants, effective July 8, 2011. The document indicated that FDA was withdrawing approval of the following three ANDAs after receiving a request from the ANDA holder, A.H. Robins Co., c/o Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101–8299: ANDA 086661, DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Elixir; ANDA 086676, DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Tablets; and ANDA 086677, DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Capsules. Before withdrawal of these ANDAs became effective, PBM Pharmaceuticals, Inc., acquired the rights to the ANDAs and informed FDA that it did not want them withdrawn. Because the basis for withdrawal would have been a request from the ANDA holder and the request was timely withdrawn, the approval of ANDAs 086661, 086676, and 086677 is still in effect.

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993–0002, (301) 796–3601.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011–14164 appearing on page 33310, in the **Federal Register** of Wednesday, June 8, 2011, the following correction is made:

On page 33313, in Table 1, the entries for ANDAs 086661, 086676, and 086677 are removed.

Dated: December 16, 2011.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2011–32822 Filed 12–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: National Institute of Mental Health (NIMH), HHS.

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, NIMH has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

DATES: Comments must be submitted within 30 days after publication in FR.

ADDRESSES: Written comments may be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: NIH Desk Officer, by Email to *OIRA_submission@omb.eop.gov,* or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact: Keisha Shropshire, Health Science Analyst, NIMH, Office of Science Policy, Planning, and Communication, Science Policy & Evaluation Branch, 6001 Executive Blvd., MSC 9667, MD 20892–9667, or Email your request, including your address to *kshropsh@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: *Title:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery. *Abstract:* The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

No comments were received in response to the 60-day notice published in the **Federal Register** of December 22, 2010 (75 FR 80542).

Below we provide NIMH's projected average estimates for the next three years:

Current Actions: New collection of information.

Type of Review: New Collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of Activities: 5.

Respondents: 28,450.

Annual Responses: 28,450.

Frequency of Response: Once per request.

Average Minutes per Response: 30.

Burden Hours: 4,408.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Dated: December 5, 2011.

Keisha Shropshire,

Health Science Analyst, Office of Science Policy, Planning, and Communication; Science Policy and Evaluation Branch, National Institute of Mental Health, National Institutes of Health.

[FR Doc. 2011–32834 Filed 12–21–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Rehabilitation and Motor Control.

Date: January 19, 2012.

Time: 4 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Rajiv Kumar, Ph.D., Chief, MOSS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4216, MSC 7802, Bethesda, MD 20892, (301) 435–1212, *kumarra@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 15, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–32837 Filed 12–21–11; 8:45 am]

BILLING CODE 4140–01–P