DATES: *Meeting Date:* October 17, 2006 from 9 a.m. to 3:30 p.m., e.d.t.

Deadline for Meeting Registration, Presentations, and Written Comments: October 10, 2006, 12 noon, e.d.t.

ADDRESSES: *Meeting Location:* Marriott Metro Center Hotel, 775 12th Street, NW., Washington, DC 20005, (202) 737–2200.

Meeting Registration, Presentations, and Written Comments: Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Office of External Affairs, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S1–05–06, Baltimore, MD 21244–1850 or contact Ms. Johnson via e-mail at *Lynne.Johnson@cms.hhs.gov*.

Meeting Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting Lynne Johnson at the address listed in the **ADDRESSES** section of this notice or by telephone at (410) 786–0090, by 12 noon, e.d.t., on October 10, 2006.

FOR FURTHER INFORMATION CONTACT: Lynne Johnson, (410) 786–0090. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (*http://www.cms.hhs.gov/FACA/04_APME.asp*) for additional information and updates on committee activities. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, grants to the Secretary the authority to establish an advisory panel if the Secretary finds the panel necessary and in the public interest. The Secretary signed the charter establishing this Panel on January 21, 1999 and approved the renewal of the charter on January 14, 2005. The establishment of the charter and renewal of the charter were announced in the February 17, 1999 **Federal Register** (64 FR 7899), and the January 28, 2005 **Federal Register** (70 FR 4129), respectively. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Anita B. Boles, Executive Director, Partnership for Clear Health Communications; Gwendolyn T. Bronson, SHINE/SHIP Counselor, Massachusetts SHINE Program; Dr. Yanira Cruz, President and Chief Executive Officer, National Hispanic Council on Aging; Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Nan Kirsten-Forte, Executive Vice President, Consumer Services, WebMD; Dr. Jessie C. Gruman, President and Chief Executive Officer, Center for the Advancement of Health; Betty L. Kennard, Vice President, Government Programs and Compliance, Health First Health Plans; Dr. David Lansky, Director, Health Program, Markle Foundation; Dr. Daniel Lyons, Senior Vice President, Government Programs, Independence Blue Cross; Dr. Frank B. McArdle, Manager, Hewitt Research Office, Hewitt Associates; Traci McClellan, J.D., Executive Director, National Indian Council on Aging; Dr. Keith Mueller, Professor and Section Head, Health Services Research and Rural Health Policy, University of Nebraska; Lee Partridge, Senior Health Policy Advisor, National Partnership for Women and Families; Myisha M. Patterson, National Health Coordinator, National Association for the Advancement of Colored People; Susan O. Raetzman, Associate Director, Public Policy Institute, American Association of Retired Persons; Rebecca Snead, Administrative Manager, National Alliance of State Pharmacy Association; William A. Steel, President, The National Grange; Marvin Tuttle, Jr., CAE, Executive Director and Chief Executive Officer, Financial Planning Association; Catherine Valenti, Chairperson and Chief Executive Officer, Caring Voice Coalition; and Grant Wedner, Manager, Business Development Team, Cosmix Corporation.

The agenda for the October 17, 2006 meeting will include the following:

- Recap of the previous (May 25, 2006) meeting.
- Centers for Medicare & Medicaid Services Update.
- Medicare Preventive Benefits.
- Medicare Prescription Drug Benefit Update.
- Public Comment.
- Listening Session with CMS Leadership.
- Next Steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to Lynne Johnson at the address listed in the **ADDRESSES** section of this notice no later than 12 noon, e.d.t., on October 10, 2006. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by 12 noon, e.d.t., on October 10, 2006.

Special Accommodation: Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at the address listed in the **ADDRESSES** section of this notice at least 15 days before the meeting.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Public Law 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 7, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 06–7884 Filed 9–21–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0180]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Records and Reports Concerning Experience With Approved New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing

that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 23, 2006.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Records and Reports Concerning Experience With Approved New Animal Drugs—21 CFR 518.80—(OMB Control No. 0910–0284)—Extension

Implementation of section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)) and § 514.80 (21 CFR 514.80) requires applicants of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to submit product/manufacturing defects, initial and followup reports for adverse drug experiences and lack of effectiveness of new animal drugs, increased frequency 15-day alert reports, periodic drug experience reports (annually or semi-annually in a specific format), and other reports (special drug experience reports, advertisement and promotional material submissions, and distributor statements).

This continuous monitoring of approved NADAs affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Current data on file with FDA is not adequate because animal drug effects can change over time, and less apparent effects may take years to manifest themselves.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA Forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Also, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own detection of a problem or complaints from product users or their veterinarians using FDA forms 1932 and 1932a. Form FDA 2301 is used to submit the required transmittal of periodic reports and promotional material for new animal drugs. The reporting and recordkeeping burden estimates are based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine (CVM). The total annual responses are also based on the submission of reports to the Division of Surveillance, CVM. The annual frequency of response was calculated as the total annual responses divided by the number of respondents.

In the **Federal Register** of May 19, 2006 (71 FR 29157), FDA published a 60-day notice requesting public comment on the information collection provisions. In response to this notice, FDA received seven comments, four of which required a response by CVM that are addressed as follows: One comment stated that FDA's estimate for the burden of the proposed collection of information seems unrealistic and inaccurate. The comment proposed 16 hours of response time for Drug Experience Reports (DER), and 49 hours for recordkeeping for each DER. FDA agrees that 16 hours is a reasonable response time required to make a DER report. In view of increased reporting requirements under § 514.80 (b)(4), CVM has increased the ''Hours per Response'' under this citation in ''Table 1—Estimated Annual Reporting Burden,'' from 11 to 16 hours thereby increasing the total burden hours to 19,616. The comment also proposed 49 hours response time per record for each DER. However, based on CVM's experience and previous surveys of industry, the 49 hours of response per record for each DER is excessive. In view of increased requirements, under § 514.80(e)[3], CVM has increased the ''Hours per Record'' under this citation in ''Table 2—Estimated Annual Recordkeeping Burden,'' from 10.35 to 14 hours, thereby increasing the total burden hours to 33,320.

Another comment suggested that the burden collections may be potentially reduced by: (1) Reducing submission requirements with established safety and (2) by automating the information collection system. FDA agrees with the comment regarding both suggestions. Under § 514.80(b)(4), it states for yearly periodic DER reports, an applicant may petition FDA to change the anniversary date and/or change the frequency of reporting. Regarding the comment suggesting automation of the information collection system, future burden estimates for collections of information will be considered when automated reporting requirements are implemented by FDA.

Another comment wanted to know the purpose for submitting a periodic report for a known event for a product with an established record. As previously stated, under § 514.80(b)(4), an applicant may petition FDA to change the anniversary date and/or change the frequency of reporting.

The respondents to this collection of information are applicants of approved NADAs and ANADAs.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(1)	1932	190	0.50	95	1	95
514.80(b)(2)(i)	1932	190	64.65	12,283	1	12,283
514.80(b)(2)(ii)	1932	190	31.62	6,007	1	6,007
514.80(b)(3)	1932	340	2.94	1,000	1	1,000
Voluntary reporting FDA Form 1932a for public	1923a	250	1	250	1	250

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(4)	2301	190	6.45	1,226	16	19,616
514.80(b)(5)(i)	2301	190	0.13	25	2	50
514.80(b)(5)(ii)	2301	190	4.06	772	2	1544
514.80(b)(5)(iii)	2301	530	0.11	56	2	112
Total Hours						40,957

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
514.80(e)[2]	530	36.58	19,385	0.5	9,693
514.80(e)[3]	530	4.49	2,379	14	33,320
Total					43,013

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Recordkeeping estimates for § 514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3); Form FDA 1932.
[3]Recordkeeping estimates for § 514.80(b)(2)(iii), (b)(4), (b)(5), and (c); Form FDA 2301.

The reporting and recordkeeping burden estimates for this collection of information are based on the submission of reports to the Division of Surveillance, CVM. The total annual response numbers are also based on the submission of reports to the Division of Surveillance, CVM. The annual frequency of response was calculated as the total annual responses divided by the number of respondents.

Dated: September 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–8023 Filed 9–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0105]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by October 23, 2006.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Liz Berbakos, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Environmental Impact Considerations—(OMB Control Number 0910–0322)—Extension

FDA is requesting OMB approval for the reporting requirements contained in the FDA regulation ''Environmental Impact Considerations.''

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4347), states national environmental objectives and imposes upon each Federal agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

The FDA NEPA regulations are in part 25 (21 CFR part 25). All applications or petitions requesting agency action require the submission of a claim for a categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

This collection of information is used by FDA to assess the environmental impact of agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse effects cannot be avoided, the agency uses the submitted information as the basis for preparing and circulating to the public