reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA, and the estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.

21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under 21 CFR 208.26.

21 CFR 208.26 (a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual frequency per response	Total Annual Responses	Hours Per Response	Total Hours
208.20	35	1.34	47	242	11,374
314.70(b)(3)(ii) 601.12(f)	3	1	3	24	72
208.24(e)	55,000	20	1,100,000	.0014	1540
208.26(a)	1	1	1	4	4
Total					12,990

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

Dated: January 7, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–659 Filed 1–11–05; 3:26 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Services; Submission for OMB Review; Comment Request

Request for generic clearance to collect public comments on the proposed standards of care for chimpanzees in the federally supported chimpanzee sanctuary system.

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Center for Research Services, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995 unless it displays a currently valid OMB control number.

Proposed Collection: Title: Request for Generic Clearance to collect public comments on the Proposed Standards of Care Regulations covering chimpanzees in the federally supported Chimpanzee Sanctuary System. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The Chimpanzee Health Improvement, Maintenance, and Protection Act of 2000 (Public Law 106–551) requires the Secretary of the Department of Health and Human Services to develop Standards of Care Regulations for chimpanzees in the Sanctuary System. The Act further requires the Secretary to publish the proposed standards in the **Federal Register** to provide a 60 day period for public comment on the proposed standards. Following receipt of public comments, NCRR/NIH will consider these comments in preparing the final regulations for the sanctuary system. The public includes members of the general population, interested communities (local, regional, and national organizations), and non-profit business entities. Input from the public will allow the NCRR/NIH staff to receive critical review of the standards from different stakeholders, provide a review and analyses of the burden estimated by the government, and help assure that the proposed standards are necessary and current. *Frequency of Response:* One time event. *Affected Public:* Non-profit entities serving as a contractor to the government to operate and maintain the federally supported Chimpanzee Sanctuary System. *Type of Respondents:* Non-profit businesses that possess qualified staff and resources needed to develop, operate, and maintain several hundred chimpanzees. *Estimated number of respondents:* 1–3. *Number Respondents per Response:* 1–3. *Average Burden Hours Per Response:* 15.4. *Burden Hours Requested:* 186.95. Total annualized cost to respondents is estimated at $8412.75. There is no capital, operating, and/or maintenance costs to report.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Annual number of respondents*	Annual frequency	Average burden hours	Annual burden hours per response
Reporting:				
§ 9.3(a)(7)(v)(C)	1–3	2	6	12
§ 9.6(c)(6)	1–3	3	2	6

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN—Continued

	Annual number of respondents*	Annual frequency	Average burden hours	Annual burden hours per response
§ 9.6(d)	1–3	2	0.5	1
§ 9.8(a)(4)	1–3	4	5	20
§ 9.11(a)	**1–3	1	1	12
§ 9.11(b)(1) (iii)	**1–3	6	2	12
§ 9.12(b)	1–3	1	6	6
Subtotal		20		69

* Presently, there is only one (1) respondent, the Contractor for the federally supported Chimpanzee Sanctuary System. The estimates are based upon a maximum of three (3) respondents in the future.
** *See* also § 9.5(c) & 9.5(e).

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Annual number of Respondents*	Annual frequency	Average burden hours	Annual burden hours per response
Recordkeeping:				
§ 9.3(a)(7)(v)(c)	1–3	2	2	4
§ 9.3(a)(10)	**1–3	1	8	8
§ 9.3(a)(11)	**1–3	1	8	8
§ 9.4(d)(1)	1–3	1	1	1
§ 9.4(d)(3)	1–3	1	6	6
§ 9.4(c)	1–3	3	8	24
§ 9.5(c)(4)	1–3	1	2	2
§ 9.5 (e)	1–3	1	4	4
§ 9.6(c)(8)	1–3	5	0.05	0.25
§ 9.6(c)(10)	1–3	4	0.1	0.4
§ 9.8(a)(1–4)	1–3	10	0.5	5
§ 9.8(b)	1–3	5	2	10
§ 9.9(a)(3)	1–3	12	0.2	2.4
§ 9.10(a)(1)	1–3	12	0.2	2.4
§ 9.10(a)(2)	1–3	4	3	12
§ 9.10(b)(1)	1–3	3	1.5	4.5
§ 9.11(a)	***1–3	6	1	6
§ 9.12(b)(1)	***1–3	1	3	3
Subtotal		69		102.55

** *See* § 9.5(c) & 9.5(e) also.
*** The reporting requirements for these sections vary because it is estimated that chimpanzees will be shipped 6 times per year. This requires 6 notifications of shipment to the Project Officer. It is estimated that approximately 1 of these shipments might require reporting because of undesirable conditions.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Annual number of respondents	Annual frequency	Average burden hours	Annual burden hours per response
Disclosure:				
§ 9.3(a)(10) **	1–3	6	0.5	3
§ 9.3(a)(11) **	1–3	1	0.5	1
§ 9.3(a)(13)	1–3	1	1	1
§ 9.4(c)	1–3	1	0.1	0.1
§ 9.4(d)(2)	1–3	1	0.1	0.1
§ 9.5(e)	1–3	1 x event	2	2
§ 9.5(f)(2)	1–3	<1/5	8	1.6
§ 9.6(c)(10)	1–3	4	0.1	0.4
§ 9.9(a)(3)	1–3	10	0.2	2
§ 9.10(a)(1)	1–3	10	0.2	2
§ 9.10(b)(1)	1–3	1	0.2	0.2
§ 9.11(a)	1–3	2	1	2
Subtotal		38.02		15.4
Total	1–3	127.02		186.95

** *See* 9.5(c) & 9.5(e) also.

*** The reporting requirements for these sections vary because it is estimated that chimpanzees will be shipped 6 times per year. This requires 6 notifications of shipment to the Project Officer. It is estimated that approximately 1 of these shipments might require reporting because of undesirable conditions such as inadequate food or water, unexpected death or illness, or any conditions affecting animal welfare.

Request for Comments: Written comments from the public and affected entities are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper monitoring and oversight of the care, welfare, and maintenance of the chimpanzees, (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) ways to minimize the burden of the collection of the information on those who are to respond, including the use of automated, electronic, mechanical, and other technological collection techniques or other forms of information technology.

Direct comments to OMB: Written comments and/or suggestions regarding items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. William Watson, NCRR, 6701 Democracy Boulevard, Room 954, Bethesda, MD 20892–4874, telephone (301) 345–0747 (not a toll-free number), or e-mail; *watsonwm@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: January 11, 2005.

Patricia Newman,

National Center for Research Services Project Clearance Liaison, National Institutes of Health.

[FR Doc. 05–587 Filed 1–11–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the NIH Advisory Board for Clinical Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for discussion of personal qualifications and performance, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIH Advisory Board for Clinical Research.

Date: January 31, 2005.

Open: 2 p.m. to 4 p.m.

Agenda: To review the Clinical Center operating plan, ABCR workgroups and Budget update.

Place: National Institutes of Health, Building 10, 10 Center Drive, 4–2551, CRC Medical Board Room, Bethesda, MD 20892.

Closed: 4 p.m. to 5 p.m.

Agenda: For discussion of personal qualifications and performance the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Place: National Institutes of Health, Building 10, 10 Center Drive, 4–2551, CRC Medical Board Room, Bethesda, MD 20892.

Contact Person: Maureen E. Gormley, Executive Secretary, Warren Grant Magnuson Clinical Center, National Institutes of Health, Building 10, Room 6–1610, Bethesda, MD 20892, (301) 496–2897,

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Dated: January 6, 2005.

Laverne Y, Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–632 Filed 1–11–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Naitonal Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the President's Cancer Panel.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended, because the premature disclosure of information and the discussions would likely to significantly frustrate implementation of recommendations.

Name of Committee: President's Cancer Panel.

Date: January 18, 2005.

Time: 3 p.m. to 5 p.m.

Agenda: The Panel will discuss the future focuses of the Panel with direction bearing on prepublication manuscripts on Translating Research into Clinical Practice. These manuscripts have been provided by their authors with the understanding that the Panel will not break prepublicaiton embargo conditions.

Place: National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 3A18, Bethesda, MD 20892, (Teleconference).

Contact Person: Maureen O. Wilson, PhD, Executive Secretary, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 3A18, Bethesda, MD 20892, 301/496–1148.

This meeting is being published less than 15 days prior to the meeting due to scheduling conflicts.

Any interested person may file written comments with the committee by forwarding the comments to the Contact Person listed on this notice. The comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.deainfo.nic.nih.gov/advisory/pcp/pcp.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research manpower; 93.399, cancer Control, National Institutes of Health, HHS.)

Dated: January 5, 2005.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–584 Filed 1–11–05; 8:45 am]

BILLING CODE 4140–01–M