These estimates are based on FDA's experience with previous consumer studies.

IV. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Schwartz, L., S. Woloshin, W. Black, et al., The Role of Numeracy in Understanding the Benefit of Screening Mammography, *Annals of Internal Medicine*, 127(11), 966–72, 1997.

2. Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Advertising, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf*.

3. Woloshin, S. and L. Schwartz, Direct to Consumer Advertisements for Prescription Drugs: What Are Americans Being Told, *Lancet*, 358, 1141–46, 2001.

4. Frosch, D.L., P.M. Krueger, R.C. Hornik, et al., Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising, *Annals of Family Medicine*, 5(1), 6–13, 2007.

5. Schwartz, L.M., S. Woloshin, H.G. Welch, The Drug Facts Box: Providing Consumers With Simple Tabular Data on Drug Benefit and Harm, *Medical Decision Making*, 27, 655–692, 2007.

6. Schwartz, L.M., S. Woloshin, H.G. Welch, Communicating Drug Benefits and Harms Wth a Drug Facts Box: Two Randomized Trials, *Annals of Internal Medicine*, 150, 516–527, 2009.

7. Woloshin, S., L.M. Schwartz, H.G. Welch, The Value of Benefit Data in Direct-to-Consumer Drug Ads, *Health Affairs, Web Exclusive Supplement*, W4–234–245, 2004.

8. Beyth-Marom, R., How Probable is Probable? A Numerical Translation of Verbal Probability Expressions, *Journal of Forecasting*, 1, 257–269, 1982.

9. Bowman, M.L., The Perfidity of Percentiles, *Archives of Clinical Neuropsychology*, 17, 295–303, 2002.

10. Cohen, D.J., J.M. Ferrell, N. Johnson, What Very Small Numbers Mean, *Journal of Experimental Psychology: General*, 131, 424–442, 2002.

11. Fagerlin, A., C. Wang, P.A. Ubel, Reducing the Influence of Anecdotal Reasoning on People's Health Care Decisions: Is a Picture Worth a Thousand Statistics?, *Medical Decision Making*, 25, 398–405, 2005.

12. Lipkus, I., Numeric, Verbal, and Visual Formats of Conveying Health Tasks: Suggested Best Practices and Future Recommendations, *Medical Decision Making*, 27, 697–713, 2007.

13. Fagerlin, A., P.A. Ubel, D.M. Smith, et al., Making Numbers Matter: Present and Future Research in Risk Communication, *American Journal of Health Behavior*, 31, Supplement 1: S47–56, 2007.

14. Ancker, J.S., Y. Senathirajah, R. Kukafka, et al., Design Features of Graphs in Health Risk Communication: A Systematic Review, *Journal of the American Medical Information Association*, 13, 608–618, 2006.

15. Lipkus, I., J.G. Hollands, The Visual Communication of Risk, *Journal of the National Cancer Institute Monographs*, 25, 149–163, 1999.

16. Slovic, P. and E. Peters, Risk Perception and Affect, *Current Directions in Psychological Science*, 15, 322–325, 2006.

17. Slovic, P., J. Monahan, DG MacGregor, Violence Risk Assessment and Risk Communication: The Effects of Using Actual Cases, Providing Instruction, and Employing Probability Versus Frequency Formats, *Law and Human Behavior*, 24, 271–96, 2000.

18. Peters, E., D. Vastfjall, P. Slovic, et al., Numeracy and Decision Making, *Psychological Science*, 17, 407–13, 2006.

Dated: December 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–31200 Filed 1–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0372]

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 February 4, 2010.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0322. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

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—21 CFR Part 25—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.

FDA's 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 an EIS, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency. The final EIS, including the comments received, is reviewed by the agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact.

Any final EIS would contain additional information gathered by the agency after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and the agency's responses to the comments, including any revisions resulting from the comments or other information. When the agency finds that no significant environmental effects are expected, the agency prepares a finding of no significant impact (FONSI).

Estimated Annual Reporting Burden for Human Drugs (Including Biologics in the Center for Devices and Radiological Health)

Under § 312.23(a)(7)(iv)(*e*) (21 CFR 312.23(a)(7)(iv)(*e*)), 21 CFR 314.50(d)(1)(iii), and 21 CFR 314.94(a)(9)(i), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 2008, FDA received 2,550 INDs from 2,026 sponsors; 106 NDAs from 88 applicants; 2,856 supplements to NDAs from 615 applicants; 13 biologics license applications (BLAs) from 9 applicants; 206 supplements to BLAs from 64 applicants; 835 ANDAs from 165 applicants; and 4,143 supplements to ANDAs from 224 applicants. FDA estimates that it receives approximately 10,689 claims for categorical exclusions as required under § 25.15(a) and (d), and 20 EAs as required under § 25.40(a) and (c). Based on information provided by the pharmaceutical industry, FDA estimates that it takes sponsors or applicants approximately 8 hours to prepare a claim for a categorical exclusion and approximately 3,400 hours to prepare an EA.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.15(a) and (d)	3,171	3.37	10,686	8	85,488
25.40(a) and (c)	20	1	20	3,400	68,000
Total					153,488

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

Estimated Annual Reporting Burden for Human Foods

Under 21 CFR 71.1, 171.1, 170.39, and 170.100, food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, and submission of a food contact notification for a food contact substance must contain either a claim of categorical exclusion under § 25.30 or § 25.32, or an EA under § 25.40. In 2008, FDA received 112 industry submissions. FDA received an annual average of 67 claims of categorical exclusions as required under § 25.15(a) and (d), and 45 EAs as required under § 25.40(a) and (c). FDA estimates that, on average, it takes petitioners, notifiers, or requestors approximately 3 hours to prepare a claim of categorical exclusion and approximately 210 hours to prepare an EA.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN FOODS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.15(a) and (d)	40	1.7	68	3	204
25.40(a) and (c)	24	1.9	45	210	9,450
Total					9,654

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

Estimated Annual Reporting Burden for Medical Devices

Under 21 CFR 814.20(b)(11), premarket approvals (PMAs) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an environmental assessment under § 25.40. In 2008, FDA received approximately 39 claims (original PMAs and supplements) for categorical exclusions as required under § 25.15(a) and (d), and 0 EAs as required under § 25.40(a) and (c). Based on information provided by less than 10 sponsors, FDA estimates that it takes approximately 6 hours to prepare a claim for a categorical exclusion and an unknown number of hours to prepare an EA.

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN FOR MEDICAL DEVICES[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.15(a) and (d)	39	1	39	6	234
25.40(a) and (c)	1	1	1	1	1
Total					235

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

Estimated Annual Reporting Burden for Biological Products in the Center for Biologics Evaluation and Research

Under § 312.23(a)(7)(iv)(*e*) and 21 CFR 601.2(a), IND and BLAs must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 2008, FDA received 245 INDs from 180 sponsors; 28 BLAs from 13 applicants; and 972 BLA supplements to license applications from 173 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA estimates that it received approximately 370 claims for categorical exclusion as required under § 25.15(a) and (d), and 2 EAs as required under § 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim for categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product.

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.15(a) and (d)	210	1.76	370	8	2,960
25.40(a) and (c)	2	1	2	3,400	6,800
Total					9,760

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

Estimated Annual Reporting Burden for Animal Drugs

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); § 514.8(a)(1) supplemental NADAs and ANADAs; § 511.1(b)(10) investigational new animal drug applications (INADs); and § 571.1(c) food additive petitions must contain a claim for categorical exclusion under § 25.30 or § 25.33 or an EA under § 25.40. In 2008, FDA's Center for Veterinary Medicine has received approximately 676 claims for categorical exclusion as required under § 25.15(a) and (d), and 8 EAs as required under § 25.40(a) and (c). FDA estimates that it takes sponsors/applicants approximately 5 hours to prepare a claim for a categorical exclusion and an average of 2,160 hours to prepare an EA.

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.15(a) and (d)	65	10.4	676	5	3,380
25.40(a) and (c)	6	1.3	8	2,160	17,280
Total					20,660

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

TABLE 6.—COMBINED ESTIMATED ANNUAL TOTAL BURDEN HOURS FOR ALL CENTERS

Total	193,797

In the **Federal Register** of September 9, 2009 (74 FR 46430), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Dated: December 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–31199 Filed 1–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Process Evaluation of the NIH's Roadmap Interdisciplinary Research Work Group Initiatives

SUMMARY: In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director, the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: The National Institute of Dental and Craniofacial Research of the National Institutes of Heath requests a three-year clearance for the ''Process Evaluation of the NIH Roadmap Interdisciplinary Research Work Group Initiatives,'' a new collection. This study will be used to determine whether the NIH's Interdisciplinary Research Work Group initiatives have been, and are being, conducted as planned, whether the expected outputs are being produced, and how the activities and processes associated with the initiatives can be improved. Information collected during the evaluation will be used to assess whether and how these initiatives differed from existing initiatives to determine whether these unique initiatives or mechanisms are necessary, to make decisions about whether to continue and/or to modify the programs, and to make decisions about structural or procedural changes within NIH that may be necessary to support cross-cutting interdisciplinary programs. The frequency of response is once for most respondents, and twice for a limited group. The affected public includes a limited number of individuals; *Type of respondents:* principal investigators, other grant investigators, and Initiative trainees. The annual reporting burden is as follows: *Estimated number of respondents:* 450; *Estimated number of responses per respondent:* PIs, 2; Other Investigators, 1; Trainees, 1; *Average burden hours per response:* 30 minutes; and *Estimated total annual burden hours requested:* 250 hours. The total annualized cost to respondents (calculated as the number of respondents * frequency of response * average time per response * approximate hourly wage rate) is estimated to be $4,565.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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 information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Sue Hamann, Ph.D., Science Evaluation Officer, Office of Science Policy Officer and Analysis, NIDCRD, NIH. You may reach Dr. Hamann by telephone on 301–594–4849 (this is not a toll-free number), or you may e-mail your request to Dr. Hamann at *Sue.Hamann@nih.hhs.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: December 22, 2009.

Sue Hamann,

Science Evaluation Officer, OSPA, NIDCR, National Institutes of Health.

[FR Doc. E9–31234 Filed 1–4–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–10–0004]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. Alternatively, to obtain a copy of the data collection plans and instrument, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30333; comments may also be sent by e-mail to *omb@cdc.gov*.

Comments are invited 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 a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarify 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 information technology. Written comments should be received within 60 days of this notice.

Proposed Project

National Disease Surveillance Program II. Disease Summaries (0920–0004 Exp. 5/31/2010)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (proposed), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Surveillance of the incidence and distribution of disease has been an important function of the U.S. Public Health Service (PHS) since 1878. Through the years, PHS/CDC has formulated practical methods of disease control through field investigations. The CDC National Disease Surveillance Program is based on the premise that diseases cannot be diagnosed, prevented, or controlled until existing knowledge is expanded and new ideas developed and implemented. Over the years, the mandate of CDC has broadened to include preventive health