Consultation Sessions to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Robert Bialas at *Robert.Bialas@acf.hhs.gov* either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Sessions will be summarized in each report without attribution, along with topics of concern and recommendations. Hotel and logistical information for the Consultation Sessions has been sent to tribal leaders via email and posted on the Early Childhood Learning and Knowledge Center Web site at *eclkc.ohs.acf.hhs.gov/hslc/eclkc_main_calendar/tc-2013*.

Dated: February 11, 2013.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

[FR Doc. 2013–03795 Filed 2–19–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

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 (the PRA).

DATES: Fax written comments on the collection of information by March 22, 2013.

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 emailed 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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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—(OMB Control Number 0910–0322)—Revision

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

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4327) 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 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 significant environmental impact. Sections 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 statues 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 events 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 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.

In the **Federal Register** of September 28, 2012 (77 FR 59619), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments that were PRA related were received from one commenter.

(Comment 1) The commenter indicated that FDA underestimates the hours required to complete an environmental assessment for tobacco products, and that FDA's 12 hours burden estimate per response is substantially underestimated. The commenter said, based on the commenter's experience, an environmental assessment for tobacco products should take approximately 80 hours to complete.

(Response 1) FDA agrees with this comment. Upon further review of the number of hours required to complete an environmental assessment for tobacco products, FDA has determined that 12 hours is too low an estimate and has revised the burden estimate per response for completing an environmental assessment for tobacco products from 12 to 80 hours. This revision was based upon revisiting this estimate with the Center for Tobacco Products staff and this comment. Rethinking the time to prepare an environmental assessment for tobacco products resulted in revising the burden per response to 80 hours.

(Comment 2) The commenter also encouraged the Agency to establish categorical exclusions for environmental assessments for tobacco product submittals under section 905(j) of the

Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387e(j)).

(Response 2) FDA has decided to not establish categorical exclusions for tobacco products at this time.

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

Estimated Annual Reporting Burden for Human Drugs (Including Biologics in the Center for Drug Evaluation and Research)

Under 21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 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 2011, FDA received 2,818 INDs from 2,064 sponsors, 99 NDAs from 79 applicants, 3,247 supplements to NDAs from 376 applicants, 5 biologic license applications (BLAs) from 5 applicants, 287 supplements to BLAs from 50 applicants, 895 ANDAs from 195 applicants, and 5,348 supplements to ANDAs from 299 applicants. FDA estimates that it will receive approximately 15,699 claims for categorical exclusions as required under § 25.15(a) and (d), and 10 EAs as required under § 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 3,175 respondents will submit an average of 4 applications for categorical exclusion and 10 respondents will submit an average of 1 EA. 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.

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

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	3,175	4	12,700	8	101,600
25.40(a) and (c)	10	1	10	3,400	34,000
Total					135,600

[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 from 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 2011, FDA received 97 industry submissions. FDA received an annual average of 42 claims of categorical exclusions as required under § 25.15(a) and (d), and 33 EAs as required under § 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 42 respondents will submit an average of 1 application for categorical exclusion and 33 respondents will submit an average of 1 EA. 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	42	1	42	8	336
25.40(a) and (c)	33	1	33	210	6,930
Total					7,266

[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 (PMA) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an EA under § 25.40. In 2011, FDA received approximately 52 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). Therefore, over the next 3 years, FDA estimates that approximately 52 respondents will submit an average of 1 application for categorical exclusion. 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.

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

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	52	1	52	6	312

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

Estimated Annual Reporting Burden for Biological Products, Drugs, and Medical Devices in the Center for Biologics Evaluation and Research

BLAs under 21 CFR 601.2(a), as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20), must contain either a claim of categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. In 2011, FDA received 14 BLAs from 14 applicants, and 831 BLA supplements to license applications from 153 applicants, 288 INDs from 210 sponsors, 1 NDA from 1 applicant, 37 supplements to NDAs from 9 applicants, 1 ANDA from 1 applicant, 12 supplements to ANDAs from 2 applicants, and 45 PMA supplements from 11 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 481 claims for categorical exclusion as required under § 25.15(a) and (d), and 2 EAs as required under § 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 247 respondents will submit an average of 2 applications for categorical exclusion and 2 respondents will submit an average of 1 EA. Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim of 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	247	2	494	8	3,952
25.40(a) and (c)	2	1	2	3,400	6,800
Total					10,752

[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), 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs, 21 CFR 511.1(b)(10) investigational new animal drug applications (INADs), and 21 CFR 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 2011, FDA's Center for Veterinary Medicine has received approximately 698 claims for categorical exclusion as required under § 25.15(a) and (d), and 10 EAs as required under § 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 70 respondents will submit an average of 10 applications for categorical exclusion and 10 respondents will submit an average of 1 EA. FDA estimates that it takes sponsors/applicants approximately 3 hours to prepare a claim of 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	70	10	700	3	2,100
25.40(a) and (c)	10	1	10	2,160	21,600
Total					23,700

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

Estimated Annual Reporting Burden for Tobacco Products

Under sections 905, 910, and 911 of the FD&C Act (21 U.S.C. 387j and 387k), premarket tobacco applications (PMTAs), applications for substantial equivalence (SEs), Exemption from SEs, and modified risk tobacco products must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an EA under § 25.40. When estimating the burden for tobacco products, FDA considered the environmental impacts associated with different applications. Specifically, in 2011, FDA estimated it will receive approximately 20 PMTAs and supplements from 20 respondents, 150 reports intended to demonstrate the SE of a new tobacco product from 150 respondents, 500 exemptions from SE requirements applications from 500 respondents, and 3 modified risk tobacco product applications from 3 respondents. FDA is also not accepting claims for categorical exclusions at this time, and estimates that there will be 135 EAs from 135 respondents as required under § 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 135 respondents will submit an average of 1 application for environmental assessment. Part of the information in the EA will be developed while writing other parts of a PMTA, SE., exemption from SE, or modified risk tobacco product application. Based on FDA's experience, previous information provided by potential sponsors, information provided by a commenter to this collection of information, and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA.

TABLE 6—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	135	1	135	80	10,800
Total					10,800

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

TABLE 7—ESTIMATED ANNUAL TOTAL REPORTING BURDEN FOR ALL CENTERS [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	3,586		13,998		108,300
25.40(a) and (c)	190		190		80,130
Total					188,430

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

Dated: February 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03836 Filed 2–19–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of MUC–1 Tumor Associated Antigens as Cancer Vaccines for Bladder Cancer, Breast Cancer, Colorectal Cancer, Gastric Cancer, Kidney Cancer, Liver Cancer, Lung Cancer, Ovarian Cancer, Prostate Cancer and Pancreatic Cancer

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Bavarian Nordic Immunotherapeutics (''BNIT'') located in Mountain View, CA, USA:

Intellectual Property: U.S. provisional patent application no. 61/582, 723 filed January 3, 2012 entitled ''Native and Agonist CTL Epitopes of the MUC–1 Tumor Antigen'' [HHS Ref. No. E–001–2012/0–US–01] as well as all international applications, continuation applications and divisional applications.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use will be limited to the use of Licensed Patent Rights for development of Pox-virus based vaccines for bladder cancer, breast cancer, colorectal cancer, gastric cancer, kidney cancer, liver cancer, lung cancer, ovarian cancer, prostate cancer and pancreatic cancer.''

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before March 22, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5587; Facsimile: (301) 435–4013; Email: *chatterjeesa@od.nih.gov.*

SUPPLEMENTARY INFORMATION: Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells, and not expressed or minimally expressed in normal tissues, are employed to generate a tumor-specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that results in tumor destruction. The initiation of an effective T-cell immune response to antigens requires two signals. The first one is antigen-specific via the peptide/major histocompatibility complex and the second or ''co-stimulatory'' signal is required for cytokine production, proliferation, and other aspects of T-cell activation.

Dr. Jeffrey Schlom et al. at NCI have identified 7 new agonist epitopes of the MUC–1 tumor associated antigen. Compared to their native epitope counterparts, peptides reflecting these agonist epitopes have enhanced ability to generate cytotoxic T-lymphocytes (CTL), which in turn have a greater ability to kill MUC–1 expressing human tumor cells. The agonist epitopes span both the VNTR region of MUC–1 and the C-terminus region. The epitopes encompass two major MHC alleles reflecting the majority of the population.

Along with the method of use, the technology encompasses the use of these agonist epitopes in peptide- and protein-based vaccines, with dendritic cells or other antigen presenting cells, or encoding sequences in DNA, viral, bacterial, yeast, or other types of vectors, or to stimulate T-cells in vitro for adoptive immunotherapy protocols.

The MUC–1 tumor associated antigen has been shown to be overexpressed and/or underglycosylated in a wide range of human cancers. The C-terminus region of MUC–1 (MUC–1C) has been shown to be an oncogene and has been associated with a more aggressive phenotype in several different cancers.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.