New NDAs (§ 314.50), ANDAs (§ 314.94), and BLAs (§ 601.2): Based on the number of submissions during 2005 under the approved collections of information for §§ 314.50, 314.94, and 601.2, we estimate that approximately 75 NDA applicants, 160 ANDA applicants, and 6 BLA applicants (respondents) submit applications to us annually. We estimate that these applicants (respondents) submit approximately 111 NDAs, 766 ANDAs, and 21 BLAs each year that are subject to the requirements of the final rule. As explained in section V of the final rule, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these applications, will be less than 15 minutes.

Supplements to NDAs (§ 314.70), ANDAs (§ 314.97), and BLAs (§ 601.12(f)(1) and (f)(2)): Based on the number of submissions during 2005 under the approved collections of information for §§ 314.70, 314.97, and § 601.12(f)(1) and (f)(2), we estimate that approximately 272 NDA applicants, 189 ANDA applicants, and 35 BLA applicants (respondents) submit supplements to approved applications to us annually. We estimate that these applicants (respondents) submit approximately 1,839 NDA supplements, 3,208 ANDA supplements, and 82 BLA supplements each year that are subject to the requirements of the final rule. As explained in section V of the final rule, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these applications, will be less than 15 minutes.

Annual Reports for NDAs (§ 314.81), ANDAs (§ 314.98), and BLAs (§ 601.12(f)(3)): Based on the number of submissions during 2005 under the approved collections of information for §§ 314.81, 314.98, and 601.12(f)(3), we estimate that approximately 306 NDA applicants, 333 ANDA applicants, and 4 BLA applicants (respondents) submit annual reports to us annually. We estimate that NDA applicants submit to us approximately 2,617 annual reports, ANDA applicants submit approximately 6,054 annual reports, and BLA applicants submit approximately 16 annual reports each year that are subject to the requirements of the final rule. As explained in section V of the final rule, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these submissions, will be less than 15 minutes.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
New Applications					
314.50	75	1.48	111	.25	27.75
314.94	160	4.79	766	.25	191.50
601.14[2]	6	3.50	21	.25	5.25
Supplements					
314.70	272	6.76	1,839	.25	459.75
314.97	189	16.98	3,208	.25	802
601.14[3]	35	2.34	82	.25	20.5
Annual Reports					
314.81	306	8.55	2,617	.25	654.25
314.98	333	18.18	6,054	.25	1,513.50
601.14[4]	4	4	16	.25	4
Total					3,678.50

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Applications submitted under § 601.2.
[3]Supplements submitted under § 601.12(f)(1) and (f)(2).
[4]Annual reports submitted under § 601.12(f)(3).

Dated: March 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–4506 Filed 3–28–06; 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: Proposed Collection; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in FDA regulations entitled ''Environmental Impact Considerations.''

DATES: Submit written or electronic comments on the collection of information by May 30, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Environmental Impact Considerations—Part 25 (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.

The FDA NEPA regulations are at 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. 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 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 (EPA). 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

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 2005, FDA received 1,933 INDs from 1,517 sponsors, 114 NDAs from 94 applicants, 2,682 supplements to NDAs from 293 applicants, 777 ANDAs from 161 applicants, and 4,318 supplements to ANDAs from 219 applicants. FDA estimates that it receives approximately 9,813 claims for categorical exclusions as required under § 25.15(a) and (d), and 11 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[1]

Estimated Annual Reporting Burden for Human Drugs					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	2,284	4.32	9,813	8	78,504
25.40(a) and (c)	11	1	11	3,400	37,400
Total					115,904

[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 (FCN) 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. From 2003 to 2005, FDA received an annual average of 88 industry submissions. FDA estimates that it received an annual average of 57 claims of categorical exclusions as required under § 25.15(a) and (d), and 31 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[1]

Estimated Annual Reporting Burden for Human Foods					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	57	1.4	80	3	240
25.40(a) and (c)	31	1.3	39	210	8,190
Total					8,430

[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 (original premarket approval applications (PMAs) and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an EA under § 25.40. In 2005, FDA received 282 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 less than 1 hour to prepare a claim for a categorical exclusion and an unknown number of hours to prepare an EA.

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Estimated Annual Reporting Burden for Medical Devices					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	47	6	282	1	282
25.40(a) and (c)	0	0	0	0	0
Total					282

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

Estimated Annual Reporting Burden for Biological Products

Under 21 CFR 312.23(a)(7)(iv)(e) and 601.2(a), IND and biologics license applications (BLAs) must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 2005, FDA received 565 INDs from 426 sponsors, 27 BLAs from 12 applicants, and 737 BLA supplements to license applications from 205 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 666 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[1]

Estimated Annual Reporting Burden for Biological Products					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	459	1.45	666	8	5,328
25.40(a) and (c)	2	1	2	3,400	6,800
Total					12,128

[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), § 570.35 (c)(1)(viii) generally recognized as safe (GRAS) affirmation petitions, 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 2005, FDA's Center for Veterinary Medicine (CVM) has received approximately 421 claims for categorical exclusion as required under § 25.15(a) and (d), and 14 EAs as required under § 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors/applicants approximately 8 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[1]

Estimated Annual Reporting Burden for Animal Drugs					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	135	3.9	421	8	3,368
25.40(a) and (c)	12	1.6	14	2,160	30,240
Total					33,608

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

Based on information provided by industry, FDA estimates that the combined annual total burden hours for all Centers is 170,352.

Dated: March 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–4507 Filed 3–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Automated Commercial Environment (ACE): Ability of Truck Carriers To Use Third Parties To Submit Manifest Information in the Test of the ACE Truck Manifest System

AGENCY: Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that the Bureau of Customs and Border Protection (CBP) will permit truck carriers who are not Automated Commercial Environment (ACE) Truck Carrier Accounts to use third parties to transmit truck manifest information on their behalf electronically in the ACE Truck Manifest system, via electronic data interchange (EDI) messaging. Truck carriers electing to use a third party to submit manifest information to CBP must possess a valid Standard Carrier Alpha Code (SCAC) from the National Motor Freight Traffic Association. Truck carriers who elect to use this transmission method will not have access to operational data and will not receive status messages on ACE transactions, nor will they have access to integrated Account data from multiple system sources. These truck carriers will be able to obtain release of their cargo, crew, conveyances, and equipment via EDI messaging back to the transmitter of the information. By making these changes, CBP is opening the test to parties previously ineligible to participate.

DATES: *Effective Date:* Truck carriers will be able to participate in ACE through the use of a third party transmitter starting on March 29, 2006.

FOR FURTHER INFORMATION CONTACT: Mr. James Swanson, via e-mail at *james.d.swanson@dhs.gov*.

SUPPLEMENTARY INFORMATION:

Background

On February 4, 2004 and September 13, 2004, CBP published General Notices in the **Federal Register** (69 FR 55167 and 69 FR 5360) announcing a test, in conjunction with the Federal Motor Carrier Safety Administration (FMCSA), allowing participating truck carriers to transmit electronic manifest data in ACE, including advance cargo information as required by section 343(a) of the Trade Act of 2002, as amended by the Maritime Transportation Security Act of 2002 (see 68 FR 68140). The advance cargo information requirements are detailed in the final rule published in the **Federal Register** at 68 FR 68140 on December 5, 2003. Truck carriers participating in the test opened up Truck Carrier Accounts which provided them with the ability to electronically transmit truck manifest data and obtain release of their cargo, crew, conveyances, and equipment via the ACE Portal or electronic data interchange (EDI) messaging.