

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN¹

| 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 |

¹There 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 BURDEN¹

| 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 |

¹There 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.

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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.

In the September 13, 2004 notice, CBP stated that, in order to be eligible for participation in this test, a carrier must have:

1. Submitted an application (*i.e.*, statement of intent to establish an ACE Account and to participate in the testing of electronic truck manifest functionality) as set forth in the February 4, 2004, **Federal Register** notice (69 FR 5360);

2. Provided a Standard Carrier Alpha Code(s) (SCAC);

3. Provided the name, address, and e-mail of a point of contact to receive further information.

In addition, participants intending to use the ACE Secure Data Portal as the means to file the manifest must submit a statement certifying the ability to connect to the Internet. Participants intending to use an EDI interface are required to first test their ability to send and receive electronic messages in either American National Standards Institute (ANSI) X12 or United Nations / Directories for Electronic Data Interchange for Administration, Commerce and Transport (UN/EDIFACT) format with CBP. The September 13, 2004 notice indicated that acceptance into this test does not guarantee eligibility for, or acceptance into, future technical tests.

Implementation

Through this notice, CBP announces a change whereby truck carriers no longer have to open ACE Truck Carrier Accounts to participate in the ACE test. Specifically, truck carriers may elect to use a third party to submit electronic manifest information via EDI to CBP. Truck carriers participating in this fashion will not have access to operational data and will not receive status messages on ACE Accounts, 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.

If the third party transmitting the truck manifest information to CBP does not use EDI, but instead wishes to use the ACE portal, the truck carrier who is submitting that information to the third party (for transmission to CBP) must have an ACE Truck Carrier Account as described in the February 4, 2004, General Notice (69 FR 5360).

A truck carrier using a third party to transmit via EDI cargo, crew, conveyance and equipment information to CBP must have a Standard Carrier Alpha Code (SCAC). Any truck carrier with a SCAC may arrange to have a

third party transmit manifest information to CBP via EDI consistent with the requirements of the ACE Truck Manifest Test.

Previous Notices Continue To Be Applicable

All of the other aspects of the ACE Truck Manifest Test as set forth in the September 13, 2004, notice (69 FR 55167), as modified by the General Notice published in the **Federal Register** (70 FR 13514) on March 21, 2005, continue to be applicable. (The March 21, 2005 notice clarified that all relevant data elements are required to be submitted in the automated truck manifest submission.) All of the aspects of the February 4, 2004, notice (69 FR 5360) also continue to be applicable, except as revised in this notice.

Dated: March 22, 2006.

Jayson P. Ahern,

Assistant Commissioner, Office of Field Operations.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Waccamaw National Wildlife Refuge

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent to prepare a Comprehensive Conservation Plan and Environmental Assessment for Waccamaw National Wildlife Refuge in Horry, Georgetown, and Marion Counties, South Carolina.

SUMMARY: This notice advises the public that the Fish and Wildlife Service, Southeast Region, intends to gather information necessary to prepare a comprehensive conservation plan and environmental assessment pursuant to the National Environmental Policy Act and its implementing regulations.

The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, requires the Service to develop a comprehensive conservation plan for each national wildlife refuge. The purpose in developing a comprehensive conservation plan is to provide refuge managers with a 15-year strategy for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and Service policies. In addition to outlining broad management

direction on conserving wildlife and their habitat, plans identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation.

The purpose of this notice is to achieve the following:

- (1) Advise other agencies and the public of our intentions, and
- (2) Obtain suggestions and information on the scope of issues to include in the environmental document.

DATES: To ensure consideration, written comments must be received no later than April 28, 2006.

ADDRESSES: Comments, questions, and requests for more information regarding the Waccamaw National Wildlife Refuge planning process should be sent to: M. Craig Sasser, Refuge Manager, 1601 North Fraser Street, Georgetown, South Carolina 29440; Telephone: 843/527-8069 or 843-509-1514; E-mail: marshall_sasser@fws.gov.

SUPPLEMENTARY INFORMATION: The Service has initiated comprehensive conservation planning for Waccamaw National Wildlife Refuge for the management of its natural resources. This planning will result in the development of goals, objectives, and strategies to carry out the refuge's purposes and to comply with laws and policies governing management and public use of refuges. Opportunities will be provided for public input at open houses to be held in both Georgetown and Conway, South Carolina. All comments received from individuals become part of the official public record. Requests for such comments will be handled in accordance with the Freedom of Information Act and the Council on Environmental Quality's NEPA regulations [40 CFR 1505.6(f)].

The refuge has an acquisition boundary that spans more than 55,000 acres and includes large sections of the Waccamaw and Great Pee Dee rivers and a small section of the Little Pee Dee River. The wetland diversity of this refuge is what sets it apart from most other found along the east coast. Wetland habitats range from historic, broken and actively managed tidal rice fields, to black water and alluvial flood plain forested wetlands. These tidal freshwater wetlands are some of the most diverse freshwater wetland system found in North America and they offer many important habitats for migratory birds, fish, and resident wildlife.

Authority: This notice is published under the authority of the National Wildlife Refuge