

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	415	1.68	699	8	5,592
25.40(a) and (c)	2	1	2	3,400	6,800
Total					12,392

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

#### Estimated Annual Reporting Burden for Animal Drugs

Under § 514.1(b)(14) (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, 21 CFR 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. Since the last OMB approval of these collections of information, FDA's Center of Veterinary Medicine has received approximately 547 claims for

categorical exclusion as required under § 25.15(a) and (d), and 19 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 FOR ANIMAL DRUGS<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	139	3.9	542	8	4,336
25.40(a) and (c)	14	1.4	19	2,160	41,040
Total					45,376

<sup>1</sup> 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 burden for the environmental

impact considerations—part 25 is as follows:

TABLE 6.—ESTIMATED ANNUAL REPORTING BURDEN FOR ALL CENTERS<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	2,735	17.5	10,768	29	81,032
25.40(a) and (c)	56	5.1	74	9,199	129,150
Total					210,182

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of March 17, 2003 (68 FR 12702), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: June 19, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-16107 Filed 6-25-03; 8:45 am]

BILLING CODE 4160-01-S

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 03N-0066]

#### Agency Information Collection Activities; Announcement of OMB Approval; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled

“Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 28, 2003 (68 FR 22388), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to,