

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN FOODS¹—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
Total					6,858

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 EA under § 25.40. In 1998, FDA received 568 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 FOR MEDICAL DEVICES¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	94	6	568	1	568
25.40(a) and (c)	0	0	0	0	0
Total					568

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 2001, FDA received 535 INDs

from 376 sponsors, 80 BLAs from 22 applicants, and 837 BLA supplements to license applications from 168 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 699 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 PRODUCTS¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	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

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

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and 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. 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 DRUGS¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	139	3.9	549	8	4,392
25.40(a) and (c)	14	1.4	19	2,160	41,040
Total					45,432

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 burden for the Environmental Impact Considerations is as follows: