

applicants. FDA estimates that it receives approximately 8,771 claims for categorical exclusions as required under § 25.15(a) and (d), and 22 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.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	2,031	4.32	8,773	8	70,184
25.40(a) and (c)	22	1	22	3,400	74,800
Total					144,984

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 premarket

notification for a food contact substance must contain a claim of categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. In 2002, FDA received 12 food additive petitions and 106 food contact substance notifications. FDA estimates that it received approximately 87 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 it takes petitioners or requestors approximately 8 hours to prepare a claim of categorical exclusion and approximately 210 hours to prepare an EA.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN FOODS¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	56	1.6	89	4	356
25.40(a) and (c)	18	1.7	31	210	6,510
Total					6,866

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 Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	94	6	564	1	564
25.40(a) and (c)	0	0	0	0	0
Total					564

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.