

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Average Hours per Response	Total Operating & Maintenance Costs	Total Hours
CAPs						
70.25	0	1	0	0	0	0
71.1	2	1	2	1,652	\$5,600	3,304
FDA Form 3504	1	1	1	1	0	1
GRAS Af- firmation Petitions						
170.35	1	1	1	2,598		2,598
FAPs						
171.1	7	1	7	3,640		25,480
FDA Form 3503	2	1	2	1		2
Total					\$5,600	31,385

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

The estimate of burden for FAPs and CAPs is based on the average number of new FAPs and CAPs received in calendar years 2000 through 2002 and the total hours expended in preparing the petitions. Although the burden varies with the type of petition submitted, an average FAP or CAP, or GRAS affirmation petition, involves analytical work and appropriate toxicological studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Electronic submissions of petitions contain the same petition information required for paper submission. The agency estimates that up to 30 percent of the petitioners for both food and color additives will take advantage of the electronic submission process. By using the guidelines and forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed for FDA's safety review. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the

electronic submission application form (Form 3503 or 3504, as appropriate) because they will have already used the guidelines to organize the petition information needed for the submission.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for § 70.25 and § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling

requirements under parts 172, 173, 175 through 178, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: March 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-8265 Filed 4-3-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P-0057]

Determination That Albuterol Sulfate Inhalation Solution 0.5% Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.