

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
7.42	1,933	1	1,933	1.8	3,479
7.46 and 7.49	1,933	1	1,933	4.0	7,732
7.53	1,933	1	1,933	36.0	69,588
7.55(b)	1,933	1	1,933	2.0	3,866
Total					84,665

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

Dated: April 24, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-10707 Filed 4-30-01; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1489]

#### Agency Information Collection Activities; Announcement of OMB Approval; Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 18, 2000 (65 FR 56314), 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, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0353. The approval expires on March 31, 2004. A copy of the supporting statement for this information collection is available on

the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 24, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-10708 Filed 4-30-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97N-0511]

#### Agency Information Collection Activities; Announcement of OMB Approval; Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 19, 2001 (66 FR 6138 at 6194), 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, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the

information collection and has assigned OMB control number 0910-0466. The approval expires on March 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 24, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-10709 Filed 4-30-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1502]

#### Agency Information Collection Activities; Announcement of OMB Approval; Adverse Experience Reporting for Licensed Biological Products and General Records

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Adverse Experience Reporting for Licensed Biological Products and General Records" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 26, 2000 (65 FR 81528), 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,



a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0308. The approval expires on April 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 24, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-10710 Filed 4-30-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1503]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Orphan Drug Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by May 31, 2001.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Orphan Drug Products—21 CFR Part 316 (OMB Number 0910-0167)—Extension

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa through 360dd) give FDA statutory authority to: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an "open protocol" basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications.

Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the application under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

In the **Federal Register** of September 19, 2000 (65 FR 56586), the agency requested comments on the proposed collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
316.10, 316.12, and 316.14	0	0	0	0	0
316.20, 316.21, and 316.26	90	1.78	160.20	125	20,025
316.22	5	1	5	2	10
316.27	5	1	5	4	20
316.30	450	1	450	2	900
316.36	.2	3	.6	15	9
Total Burden Hours					20,964

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

The information requested from respondents represents, for the most part, an accounting of information already in possession of the applicant. It is estimated, based on the frequency of requests over the past 10 years, that

90 persons or organizations per year will request orphan drug designation and that no requests for recommendations on design of preclinical or clinical studies will be received. Based upon FDA experience

over the last decade, FDA estimates that the effort required to prepare applications to receive consideration for sections 525 and 526 of the act (§§ 316.10, 316.12, 316.20, and 316.21) is generally similar and is estimated to