

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

21 CFR Sections	No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
120.11(a)(1)(iv), 120.11 (a)(2), and 120.12 (a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.14(a)(2) and 120.14(c) and (d)	308	1	308	12	3,696
Total hours					360,930

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

Table 1 provides a breakdown of the total estimated annual recordkeeping burden. The estimates in this table have been reviewed by the agency's HACCP experts, who have practical experience in observing various processing operations and related recordkeeping activities.

The burden estimates in table 1 are based on an estimate of the total number of juice manufacturing plants (i.e., 2,300) affected by the regulations. Included in this total are 850 plants currently identified in FDA's official establishment inventory plus 1,220 very small apple juice manufacturers and 230 very small orange juice manufacturers. The total burden hours are derived by estimating the number of plants affected by each portion of this final rule and multiplying the corresponding number by the number of records required annually and the hours needed to complete the record. These numbers were obtained from the agency's final regulatory impact analysis prepared for these regulations.

Moreover, these estimates assume that every processor will prepare sanitary standard operating procedures and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under these regulations.

Dated: April 15, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0329]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine," has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 26, 2004 (69 FR 3586), 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 0910-0454. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 14, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0327]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation," has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 26, 2004 (69 FR 3587), 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