addition, table 2 of this document sets out estimated reporting burdens for HCT/P listing updates and establishment location or ownership amendments that would occur during any given year. If there is no change to an HCT/P listing, establishment location or ownership, a submission is not required. It is estimated that ongoing annual registration, updates and amendments require 0.50 hour, while the initial submission requires on average 0.75 hour. In addition, table 2 of this document shows that the average hours per response is 0.25 hour for the HCT/P listing updates and location/ownership amendments, which are required only when a change is made. In table 2 of this document, we also estimate that approximately 5 percent of the 1,159 establishments, or 58 establishments, will make changes to HCT/P's, location, or ownership in any one year after the initial registration and listing.

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

TABLE 1.—ESTIMATED INITIAL (ONE-TIME) REPORTING BURDEN[1]

21 CFR Section	Form FDA 3356	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
207.20(f)		1	1	1	0.5	0.5
807.20(f)		65	1	65	0.5	32.5
1271.10(b) and 1271.25(a) and (b)	Inital registration and listing	1,159	1	1,159	0.75	869.25
Total						902.25

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form FDA 3356	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1271.10(b) and 1271.21(b)	Annual registration	1,159	1	1,159	0.5	579.5
1271.10(b), 1271.21(c), and 1271.25(c)	Listing update	58	1	58	0.5	29
1271.10(b) and 1271.26	Location/ownership amendment	58	1	58	0.25	14.5
Total						623

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

Dated: December 5, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31592 Filed 12–11–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1353]

Agency Information Collection Activities; Announcement of OMB Approval; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components'' 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 July 6, 2000 (65 FR 41674), 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 0910–0116. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: December 5, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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