TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Form No.	No. of Respondents;	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1020.30(h)(1) through (h)(4) and 1020.32(a)(1) and (g)		200	1.33	265	35	9,275
1020.32(g) and 1020.33(c), (d), (g)(4), (j)(1), and (j)(2)		9	1	9	40	360
1020.40(c)(9)(i) and (c)(9)(ii)		8	1	8	40	320
1030.10(c)(4)		41	1.61	66	20	1,320
1030.10(c)(5)(i) through (c)(5)(iv)		41	1.61	66	20	1,320
1030.10(c)(6)(iii) and (c)(6)(iv)		1	1	1	1	1
1040.10(a)(3)(i)		83	1	83	3	249
1040.10(h)(1)(i) through (h)(1)(vi)		805	1	805	8	6,440
1040.10(h)(2)(i) and (h)(2)(ii)		100	1	100	8	800
1040.11(a)(2)		190	1	190	10	1,900
1040.11(c)	FDA 3147	53	2.2	115	0.5	58
1040.20(d), (e)(1), and (e)(2)		110	1	110	10	1,100
1040.30(c)(1)		1	1	1	1	1
1040.30(c)(2)		7	1	7	1	7
1050.10(f)(1) through (f)(2)(iii)		10	1	10	56	560
Total						89,278

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505
1002.40 and 1002.41	2,950	49.2	145,140	2.4	7,080
1020.30(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1.0	83
Total					235,679

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

The burden estimates were derived by consultation with FDA and industry personnel and actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in the ''Estimated Annual Reporting Burden'' table.

The following information collection requirements are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); and 1005.21(a) through (c). These requirements ''apply to the collection of information during the conduct of general investigations or audits'' (5 CFR 1320.4(b)). The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: May 26, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–13892 Filed 6–2–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0529]

Agency Information Collection Activities; Announcement of OMB Approval; Changes to an Approved NDA or ANDA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Changes to an Approved NDA or ANDA'' 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 January 6, 2000 (65 FR 779), 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 0910–0431. The approval expires on February 28, 2001. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 26, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–13891 Filed 6–2–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0725]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Interstate Shellfish Dealers Certificate

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 July 5, 2000.

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: Desk Officer for FDA.

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

Interstate Shellfish Dealers Certificate—(OMB Control Number 0910–0021)—Extension

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP). The NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate.'' FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List,'' a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, the NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

In the **Federal Register** of March 7, 2000 (65 FR 12013), 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 [1]

Form No.	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
FDA 3038	35	58	2,036	.10	204

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