

Under § 601.6(a), the number of respondents (21) is based on FDA estimates that establishments would need to notify an average of 20 selling agents and distributors of such suspension and provide FDA with the

records of such notification. The number of respondents is based on the estimated annual number of suspensions by FDA of an establishment or product license(s). The estimated burden hours includes the time to

prepare a notification letter and submit record of such notification to FDA.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Form FDA No.	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total Hours
601.2(a)	2567 and 356h ²	17	3.71	63	2	126
601.12(f)(1)	2567	12	1	12	40	480
601.12(f)(2)	2567	10	1	10	20	200
601.12(f)(3)	2567	70	1.43	100	10	1,000
601.12(f)(4) and 601.45	2567	63	33.03	2,081	10	20,810
601.12(b)(1) and (b)(3)	356h ²	190	4.75	903	80	72,240
601.12(c)(1) and (c)(3)	356h ²	98	2.60	255	50	12,750
601.12(c)(5)	356h ²	34	1.21	41	50	2,050
601.12(d)	356h ²	166	1.37	227	10	2,270
601.12(e)	356h ²	14	1.43	20	20	400
600.15(b)	356h ²	1	1	1	8	8
610.53(d)	356h ²	1	1	1	8	8
601.25(b)(3)	NA	0	0	0	0	0
601.26(f)	NA	0	0	0	0	0
601.5(a)	NA	33	1	33	.33	11
601.6(a)	NA	2	10.50	21	.33	7
Total						112,360

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

² The burden hours for the use of Form FDA 356h are reported under OMB Control No. 0910-0427.

Dated: February 29, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-0725]

Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealers Certificate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on

Form 3038, "Interstate Shellfish Dealer's Certificate."

DATES: Submit written comments on the collection of information by May 8, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each

proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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.

This estimate is based on the numbers of certificates received in 1999.

Dated: February 29, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-5469 Filed 3-6-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2553]

Agency Information Collection Activities; Announcement of OMB Approval; Citizen Petition—21 CFR 10.30

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Citizen Petition—21 CFR 10.30" 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 10, 1999 (64 FR 69271), 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 0910-0183. The approval expires on February 28, 2003. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 29, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-5418 Filed 3-6-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2875]

Agency Information Collection Activities; Announcement of OMB Approval; Blood Establishment Registration and Product Listing—Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Blood Establishment Registration and Product Listing—Form FDA 2830" 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 20, 1999 (64 FR 71144), 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 0910-0052. The approval expires on February 28, 2003. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 29, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-5466 Filed 3-6-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00F-0812]

Bayer Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing