Medicare Coordinator, Cahaba GBA, Station 7, 636 Grand Avenue, Des Moines, IA 50309–2551.
Medicare Coordinator, Kansas B/C, P.O. Box 239, 1133 Topeka Ave., Topeka, KS 66629–0001.
Medicare Coordinator, Nebraska B/C, P.O. Box 3248, Main PO Station, Omaha, NE 68180–0001.
Medicare Coordinator, Mutual of Omaha, P.O. Box 1602, Omaha, NE 68101.
Medicare Coordinator, Montana B/C, P.O. Box 5017, Great Falls Div., Great Falls, MT 59403–5017.
Medicare Coordinator, Noridian, 4510 13th Avenue SW., Fargo, ND 58121–0001.
Medicare Coordinator, Utah B/C, P.O. Box 30270, 2455 Parleys Way, Salt Lake City, UT 84130–0270.
Medicare Coordinator, Wyoming B/C, 4000 House Avenue, Cheyenne, WY 82003.
Medicare Coordinator, Arizona B/C, P.O. Box 37700, Phoenix, AZ 85069.
Medicare Coordinator, UGS, P.O. Box 70000, Van Nuys, CA 91470–0000.
Medicare Coordinator, Regents BC, P.O. Box 8110 M/S D–4A, Portland, OR 97207–8110.
Medicare Coordinator, Premera BC, P.O. Box 2847, Seattle, WA 98111–2847.

4. Medicare Carriers

Medicare Coordinator, NHIC, 75 Sargent William Terry Drive, Hingham, MA 02044.
Medicare Coordinator, B/S Rhode Island (RI BS), 444 Westminster Street, Providence, RI 02903–2790.
Medicare Coordinator, Trailblazer Health Enterprises, Meriden Park, 538 Preston Ave., Meriden, CT 06450.
Medicare Coordinator, Upstate Medicare Division, 11 Lewis Road, Binghamton, NY 13902.
Medicare Coordinator, Empire Medicare Services, 2651 Strang Blvd., Yorktown Heights, NY, 10598.
Medicare Coordinator, Empire Medicare Services, NJ, 300 East Park Drive, Harrisburg, PA 17106.
Medicare Coordinator, Triple S, #1441 F.D., Roosevelt Ave., Guaynabo, PR 00968.
Medicare Coordinator, Group Health Inc., 4th Floor, 88 West End Avenue, New York, NY 10023.
Medicare Coordinator, Highmark, P.O. Box 89065, 1800 Center Street, Camp Hill, PA 17089–9065.
Medicare Coordinator, Trailblazers Part B, 11150 McCormick Drive, Executive Plaza 3 Suite 200, Hunt Valley, MD 21031.
Medicare Coordinator, Trailblazer Health Enterprises, Virginia, P.O. Box 26463, Richmond, VA 23261–6463.
United Medicare Coordinator, Tricenturion, 1 Tower Square, Hartford, CT 06183.
Medicare Coordinator, Alabama B/S, 450 Riverchase Parkway East, Birmingham, AL 35298.
Medicare Coordinator, Cahaba GBA, 12052 Middleground Road, Suite A, Savannah, GA 31419.
Medicare Coordinator, Florida B/S, 532 Riverside Ave, Jacksonville, FL 32202–4918.
Medicare Coordinator, Administar Federal, 9901 Linnstation Road, Louisville, KY 40223.
Medicare Coordinator, Palmetto GBA, 17 Technology Circle, Columbia, SC 29203–0001.
Medicare Coordinator, CIGNA, 2 Vantage Way, Nashville, TN 37228.
Medicare Coordinator, Railroad Retirement Board, 2743 Perimeter Parkway, Building 250, Augusta, GA 30999.
Medicare Coordinator, Cahaba GBA, Jackson, Miss, P.O. Box 22545, Jackson, MS 39225–2545.
Medicare Coordinator, Adminastar Federal (IN), 8115 Knue Road, Indianapolis, IN 46250–1936.
Medicare Coordinator, Wisconsin Physicians Service, P.O. Box 8190, Madison, WI 53708–8190.
Medicare Coordinator, Nationwide Mutual Insurance Co., P.O. Box 16788, 1 Nationwide Plaza, Columbus, OH 43216–6788.
Medicare Coordinator, Arkansas B/S, 601 Gaines Street, Little Rock, AR 72203.
Medicare Coordinator, Arkansas—New Mexico, 601 Gaines Street, Little Rock, AR 72203.
Medicare Coordinator, Palmetto GBA—DMERC, 17 Technology Circle, Columbia, SC 29203–0001.
Medicare Coordinator, Trailblazer Health Enterprises, 901 South Central Expressway, Richardson, TX 75080.
Medicare Coordinator, Nordian, 636 Grand Avenue, Des Moines, IA 50309–2551.
Medicare Coordinator, Kansas B/S, P.O. Box 239, 1133 Topeka Ave., Topeka, KS 66629–0001.
Medicare Coordinator, Kansas B/S—NE, P.O. Box 239, 1133 Topeka Ave., Topeka, KS 66629–0239.
Medicare Coordinator, Montana B/S, P.O. Box 4309, Helena, MT 59601.
Medicare Coordinator, Nordian, 4305 13th Avenue South, Fargo, ND 58103–3373.
Medicare Coordinator, Noridian Bcbsnd (C0), 730 N. Simms #100, Golden, CO 80401–4730.
Medicare Coordinator, Noridian Bcbsnd (WY), 4305 13th Avenue South, Fargo, ND 58103–3373.
Medicare Coordinator, Utah B/S, P.O. Box 30270, 2455 Parleys Way, Salt Lake City, UT 84130–0270.
Medicare Coordinator, Transamerica Occidental, P.O. Box 54905, Los Angeles, CA 90054–4905.
Medicare Coordinator, NHIC—California, 450 W. East Avenue, Chico, CA 95926.
Medicare Coordinator, Cigna, Suite 254, 3150 Lakeharbor, Boise, ID 83703.
Medicare Coordinator, Cigna, Suite 506, 2 Vantage Way, Nashville, TN 37228.

Payment Safeguard Contractors

Medicare Coordinator, Aspen Systems Corporation, 2277 Research Blvd., Rockville, MD 20850.
Medicare Coordinator, DynCorp Electronic Data Systems (EDS), 11710 Plaza America Drive, 5400 Legacy Drive, Reston, VA 20190–6017.
Medicare Coordinator, Lifecare Management Partners Mutual of Omaha Insurance Co., 6601 Little River Turnpike, Suite 300, Mutual of Omaha Plaza, Omaha, NE 68175.
Medicare Coordinator, Reliance Safeguard Solutions, Inc., P.O. Box 30207, 400 South Salina Street, 2890 East Cottonwood Pkwy., Syracuse, NY 13202.
Medicare Coordinator, Science Applications International, Inc., 6565 Arlington Blvd. P.O. Box 100282, Falls Church, VA.
Medicare Coordinator, California Medical Review, Inc., Integriguard Division Federal Sector Civil Group One, Sansome Street, San Francisco, CA 94104–4448.
Medicare Coordinator, Computer Sciences Corporation, Suite 600, 3120 Timanus Lane, Baltimore, MD 21244.
Medicare Coordinator, Electronic Data Systems (EDS), 11710 Plaza America Drive, 5400 Legacy Drive, Plano, TX 75204.
Medicare Coordinator, TriCenturion, L.L.C., P.O. Box 100282, Columbia, SC 29202.

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BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0328]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by December 15, 2006.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Food Additive Petitions—21 CFR Part 571 (OMB Control Number 0910–0546)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the act (21 U.S.C. 348(b)) specifies the information that must be submitted by a petition in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provision of section 409 of the act (21 U.S.C. 348), procedural regulations have been issued under part 571 (21 CFR part 571). These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the law. The regulations add no substantive requirements to those indicated in the law, but attempt to explain the requirements and provide a standard format for submission to speed the processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 573 and 582. The labeling regulations are considered by FDA to be cross-referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

On September 29, 2004, OMB approved a new information collection on food additive petitions submitted by the Center for Veterinary Medicine (CVM). The terms of clearance for this information collection stated that, given the interrelatedness of this collection to the information collected under OMB control number 0910–0016 by the Center for Food Safety and Applied Nutrition (CFSAN), FDA should consider merging the two collections. In consultation with CFSAN, CVM has decided not to merge these two collections, because what was once a food additive petitions approval (OMB control number 0910–0016), is now also the approval for affirmation of generally recognized as safe (GRAS) status (formerly OMB control number 0910–0132), labeling requirements for color additives (other than hair dyes) and petitions (formerly OMB control number 0910–0185), electronic submission of food and color additive petitions (formerly OMB control number 0910–0480), and substances approved for use in the preparation of meat and poultry products (formerly OMB control number 0910–0461). Thus, adding one CVM process to a collection now containing four dissimilar CFSAN processes is not justifiable any more. Finally, the CVM food additive petition process stems from a different section of the CFR and the two processes are handled separately. CVM's food additive petition process relates to part 571; CFSAN's process relates to 21 CFR part 171. There is no efficiency in discussing these separate processes in a single collection of information.

Respondents are expected to be the veterinary feed industry.

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

The estimated annual burden for this information collection is 18,000 hours.

Food additive petitions submitted to CVM are estimated to fall into one of two categories of complexity that also can be used to represent estimates of the information collection burden for food additive petitions. These include only expected petitions for food additives not eligible for exemption under new section 409(h) of the act (21 U.S.C. 348(h)).

Under § 571.1(c) moderate category, for a food additive petition without complex chemistry, manufacturing, efficacy, or safety issues, the estimated time requirement per petition is approximately 3,000 hours. An average of one petition of this type is received on an annual basis, resulting in a burden of 3,000 hours.

Under § 571.1(c) complex category, for a food additive petition with complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. An average of one petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

Under § 571.6, for a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of four petitions of this type are received on an annual basis, resulting in a burden of 5,200 hours.

In the **Federal Register** of September 1, 2006 (71 FR 52124), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	3,000	3,000
571.1(c) complex category	1	1	1	10,000	10,000
571.6	2	2	4	1,300	5,200
Total					18,200

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

Dated: November 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–19201 Filed 11–14–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0452]

Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization

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 information collection requirements relating to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further processing, labeling, or repacking.

DATES: Submit written or electronic comments on the collection of information by January 16, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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 these topics: (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.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control Number 0910–0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices that are nonsterile are being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices.

The respondents to this collection of information are device manufacturers and contact sterilizers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.150(e)	90	20	1,800	4	7,200

[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 of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
801.150(a)(2)	90	20	1,800	0.5	900

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