Equipment

Description: ''Equipment'' means an article of nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) $5,000. (Note: Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation shall be included in or excluded from acquisition cost in accordance with the organization's regular written accounting practices.)

Justification: For each type of equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use on the project, as well as use or disposal of the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy or section of its policy which includes the equipment definition.

Supplies

Description: Costs of all tangible personal property other than that included under the Equipment category.

Justification: Specify general categories of supplies and their costs. Show computations and provide other information which supports the amount requested.

Contractual

Description: Costs of all contracts for services and goods except for those which belong under other categories such as equipment, supplies, construction, etc. Third-party evaluation contracts (if applicable) and contracts with secondary recipient organizations, including delegate agencies and specific project(s) or businesses to be financed by the applicant, should be included under this category.

Justification: All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients and subrecipients, other than States that are required to use Part 92 procedures, must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 USC 403(11) currently set at $100,000. Recipients might be required to make available to ACF pre-award review and procurement documents, such as request for proposals or invitations for bids, independent cost estimates, etc.

Note: Whenever the applicant intends to delegate part of the project to another agency, the applicant must provide a detailed budget and budget narrative for each delegate agency, by agency title, along with the required supporting information referred to in these instructions.

Other

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to insurance, food, medical and dental costs (noncontractual), professional services costs, space and equipment rentals, printing and publication, computer use, training costs, such as tuition and stipends, staff development costs, and administrative costs.

Justification: Provide computations, a narrative description and a justification for each cost under this category.

Indirect Charges

Description: Total amount of indirect costs. This category should be used only when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency.

Justification: An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the applicant organization is in the process of initially developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested, those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgment that the applicant is accepting a lower rate than allowed.

Program Income

Description: The estimated amount of income, if any, expected to be generated from this project.

Justification: Describe the nature, source and anticipated use of program income in the budget or refer to the pages in the application which contain this information.

Nonfederal Resources

Description: Amounts of non-Federal resources that will be used to support the project as identified in Block 15 of the SF–424.

Justification: The firm commitment of these resources must be documented and submitted with the application in order to be given credit in the review process. A detailed budget must be prepared for each funding source.

Total Direct Charges, Total Indirect Charges, Total Project Costs.

[Self-explanatory]

[FR Doc. 01–11680 Filed 5–8–01; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0208]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary National Retail Food Regulatory Program Standards

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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's collection of information from local, State, and tribal agencies concerning their use of or planned use of all or part of the Voluntary National Retail Food Regulatory Program Standards.

DATES: Submit written or electronic comments on the collection of information by July 9, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. 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: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–26, Rockville, MD 20857, 301–827–4659.

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 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.

Voluntary National Retail Food Regulatory Program Standards

FDA has developed the Voluntary National Retail Food Regulatory Program Standards (the National Standards) to assist and promote the uniform application of provisions of the model FDA Food Code by several thousand local, State, and tribal jurisdictions that have primary responsibility for the regulation or oversight of retail level food operations. The National Standards are intended to serve as a guide to regulatory retail food program managers in the design and management of a retail food program that is focused on the reduction of risk factors know to cause foodborne illness. The National Standards also promote active management control by industry of all risk factors that may cause foodborne illness. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243), and delegation of authority from the Public Health Service to the Commissioner of Food and Drugs related to food protection is contained in 21 CFR 5.10(a)(2) and (a)(4). Under 31 U.S.C. 1535, FDA provides financial assistance to other Federal agencies such as the Indian Health Service. FDA has established a section on the Internet at http://vm.cfsan.fda.gov/dms/ret-toc.html under ''Federal/State Food Programs—Retail Food Safety References'' to list jurisdictions that have voluntarily elected to use the National Standards.

Utilization of the National Standards by local, State, and tribal regulatory agencies is an important step to further the goals of the President's Council on Food Safety and FDA program goals. All regulatory agencies are encouraged to voluntarily utilize the National Standards as a guide for the design and management of a retail food safety program. There is no reporting or recordkeeping requirement for those jurisdictions that wish to utilize part or all of the National Standards to enhance or measure program performance. Reporting is only a requirement for those jurisdictions that request to be listed in the FDA National Registry.

Jurisdictions that request listing in the FDA National Registry of participating regulatory agencies will be expected to perform certain management tasks and periodically report the results to FDA. Voluntary listing in the FDA National Registry requires that the following tasks be performed by State, local, and tribal program managers: (1) Conduct a program self assessment, (2) conduct a baseline survey of the regulated industry, and (3) obtain an independent outside audit. All three tasks must be completed within a 3-year time span. The tasks must be performed in accordance with the guidance provided in the National Standards and the results reported to FDA.

FDA based its estimate on the number of State agencies (100) involved in Food Code related regulatory programs, 300 local agencies with local ordinance authority that may consider Food Code adoption in any one year and 100 tribal agencies. The presumption being that those agencies most likely to utilize the National Standards are also those agencies with authority to adopt and enforce the model FDA Food Code. There is only one required report, the FDA National Registry Report (Appendix I), which is used to report program self assessment, baseline surveys of industry, and outside audits. The time required to complete the actual reporting document is minimal, however, additional time is required to analyze and review existing records, conduct baseline inspections, and secure an outside audit. The hour burden estimate includes the time required to review the instructions in the National Standards, search existing data sources, gather and maintain the data needed, complete worksheets, and review the collected information. The estimate of 92 hours to complete a program self assessment is based on the average time reported by the four State and three local jurisdictions that participated in the National Standards Pilot. The amount of time expended by individual jurisdictions ranged from 40 to 215 hours. This range is reflective of the difference in size between jurisdictions. The baseline survey of industry and the outside audit are expected to require a similar amount of time to complete. Because only one of the three tasks is required per year, the average annual reporting burden is estimated to be 92 hours per year for each participating jurisdiction.

Because the records of establishment inspections, investigations, and enforcement activities are routinely maintained and accepted management practices already necessitate the collection of some required information and maintenance of records, the recordkeeping burden is minimal.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Standard No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
9[2]	500	1	500	92	46,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Includes the use of Forms FDA 3519 and 3520.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Standard No.	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record-keeper	Total Hours
3, 4, and 6[2]	500	1	500	5	2,500

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The standards incorporate the best program management practices currently in use in the regulatory community. The recommended policies, procedures, and standard operating procedures contained in the various national standards are considered usual and customary management practices for State, local, and tribal agencies that regulate the retail segment of the food industry.

Dated: May 4, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11618 Filed 5–8–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0239]

Agency Information Collection Activities; Announcement of OMB Approval; Request for Resolution of Scientific Disputes Concerning the Regulation of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Request for Resolution of Scientific Disputes Concerning the Regulation of Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of February 8, 2001 (66 FR 9585), 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 0910–0467. The approval expires on April 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 3, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11583 Filed 5–8–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0179]

Purina Mills, Inc., et al.; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 11 new animal drug applications (NADAs) listed below. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove the portions reflecting approval of the NADAs because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective May 21, 2001.

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5593.

SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the NADAs listed below because the products are no longer manufactured or marketed:

Sponsor	NADA No. Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166–6812.	NADA 48–915 Purina® Bot Control (trichlorfon)	520.2520a (017800)
Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334.	NADA 97–567 Tylan® 10 Premix (tylosin phosphate).	558.625(b)(17) (021780)
.....	NADA 97–615 Swine Med-A-Mix TS 8000 Premix, Tylan® 5, 10, 20, 40 Sulfa-G (tylosin phosphate and sulfamethazine).	558.630(b)(4) and (b)(10) (021780)
Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318–1093.	NADA 110–440 Hygromix Hygrowormer Hyanthelmix (hygromycin B).	558.274(a)(2), (a)(3), (a)(4), (c)(1)(i), and (c)(1)(ii) (016968)
Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705.	NADA 44–585 Oxytocin Injection	522.1680 (000402)
.....	NADA 45–578 Lidocaine Hydrochloride with Epi-nephrine Injection 2%.	522.1258 (000402)
.....	NADA 45–737 Sodium Pentobarbital Injection ...	522.1704(b) (000402)
.....	NADA 45–848 Phenylbutazone Injection	522.1720 (000402)
.....	NADA 110–349 Dexamethasone Injection	522.540(c)(2) (000402)