when appropriate, and other forms of information technology.

Designated New Animal Drugs for Minor Use and Minor Species—21 CFR Part 516 (OMB Control No. 0910–0605)—Extension

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004 amended the Federal Food, Drug, and Cosmetic Act (the act) to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species. This legislation provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors whose drugs are "MUMS-designated" by FDA. Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species, for example, zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees. Participation in the MUMS program is completely optional for drug sponsors so the associated paperwork only applies to those sponsors who request and are subsequently granted "MUMS designation." The rule specifies the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees.

Under part 516 (21 CFR part 516), § 516.20 provides requirements on the content and format of a request for MUMS-drug designation, § 516.26 provides requirements for amending MUMS-drug designation, § 516.27 provides provisions for change in sponsorship of MUMS-drug designation, § 516.29 provides provisions for termination of MUMS-drug designation, § 516.30 provides requirements for annual reports from sponsor(s) of MUMS-designated drugs, and § 516.36 provides provisions for insufficient quantities of MUMS-designated drugs. Respondents are pharmaceutical companies that sponsor new animal drugs.

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
516.20	15	5	75	16	1,200
516.26	3	1	3	2	6
516.27	1	1	1	1	1
516.29	2	1	2	1	2
516.30	15	5	75	2	150
516.36	1	1	1	3	3
Total					1,362

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

The burden estimate for this reporting requirement was derived in FDA's Office of Minor Use and Minor Species Animal Drug Development by extrapolating the current investigational new animal drug (INAD) and new animal drug (NAD) reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: July 13, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–17609 Filed 7–19–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0374]

Agency Information Collection Activities; Proposed Collection; Comment Request; Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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 reporting requirements contained in existing FDA regulations governing petitions to request an exemption from 100 percent identity testing of dietary ingredients.

DATES: Submit either electronic or written comments on the collection of information by September 20, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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 Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR 111.75(a)(1)(ii) (OMB Control Number 0910–0608)—Extension

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) (Public Law 103–417) was signed into law. DSHEA, among other things, amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 402(g) of the act (21 U.S.C. 342(g)). Section 402(g)(2) of the act provides, in part, that the Secretary of Health and Human Services (the Secretary) may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g)(1) of the act states that a dietary supplement is adulterated if "it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations." Under section 701(a) of the act (21 U.S.C. 371(a)), FDA may issue regulations necessary for the efficient enforcement of the act.

FDA published a final rule on June 25, 2007 (72 FR 34752) (the final rule), that established, in part 111 (21 CFR part 111), the minimum Current Good Manufacturing Practice (CGMP) necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. On June 25, 2007 (72 FR 34959), FDA also published an Interim Final Rule (the IFR) establishing a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. The IFR redesignated § 111.75(a)(1) of the CGMP final rule as § 111.75(a)(1)(i) and set forth a procedure for submission of a petition to FDA in a new § 111.75(a)(1)(ii), under which manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The regulation clarifies that FDA is willing to consider, on a case-by-case basis, a manufacturer's conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use.

Section 111.75(a)(1) of the CGMP final rule reflects FDA's determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, FDA recognizes that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, FDA added to § 111.75(a)(1), an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the agency for such an exemption to 100 percent identity testing under § 10.30 and the agency grants such exemption. Such a procedure would be consistent with FDA's stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements. Section 111.75(a)(1)(ii) sets forth the information a manufacturer is required to submit in such a petition. The regulation also contains a requirement to ensure that the manufacturer keeps FDA's response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95. The collection of information in § 111.95 has been approved under OMB control number 0910–0606.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, importers, large businesses, and small businesses.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
111.75(a)(1)(ii)	1	1	1	8	8

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

In the last 3 years, FDA has not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients; therefore, the agency estimates that one or fewer petitions will be submitted annually. Although FDA has not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients in the last 3 years, it believes that these information collection provisions should be extended to provide for the potential future need of a firm in the dietary supplement industry to petition for an exemption from 100 percent identity testing of dietary ingredients. Based on our experience with petition processes, we estimate that the assembly of information in support of the petition required by § 111.75(a)(1)(ii) will take 8 hours.

Dated: July 13, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–17608 Filed 7–19–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NIH Office of Intramural Training and Education Application

Summary

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Intramural Training & Education/OIR/OD, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: NIH Office of Intramural Training & Education Application. *Type of Information Collection Request:* Revision. *Form Number:* 0925–0299. *Expiration Date:* September 30, 2012. *Need and Use of Information Collection:* The Office of Intramural Training & Education (OITE) administers a variety of programs and initiatives to recruit pre-college through post-doctoral educational level individuals into the National Institutes of Health Intramural Research Program (NIH–IRP) to facilitate develop into future biomedical scientists. The proposed information collection is necessary in order to determine the eligibility and quality of potential awardees for traineeships in these programs. The applications for admission consideration include key areas such as: Personal information, eligibility criteria, contact information, student identification number, training program selection, scientific discipline interests, educational history, standardized examination scores, reference information, resume components, employment history, employment interests, dissertation research details, letters of recommendation, financial aid history, sensitive data, future networking contact, travel information, as well as feedback questions about interviews and application submission experiences. Sensitive data collected on the applicants, race, gender, ethnicity and recruitment method, are made available only to OITE staff members or in aggregate form to select NIH offices and are not used by the admission committee for admission consideration; optional to submit.

Over the last several years the OITE has used three OMB Clearance Numbers for the collection of applications for the training programs. To improve announcement of all training programs and lessen the burden of applicants, the OITE proposes to merge the following:

- 0925–0299—NIH Intramural Research Training Award, Program Application.
- 0925–0438—Undergraduate Scholarship Program (UGSP).
- 0925–0501—Graduate Student Training Program Application.

Renewing 0925–0299 OMB Clearance Number with the new name "Office of Intramural Training & Education Application".

Frequency of Response: On occasion. *Affected Public:* Individuals seeking intramural training opportunities and references for these individuals. *Type of Respondents:* students, post-baccalaureates, technicians, graduate students, and post-doctorates. There are no capital costs, operating costs, and/or maintenance costs to report.

The annual reporting burden is displayed in the following table:

ESTIMATES OF HOUR BURDEN

Program	Estimated number of respondents	Estimated number of responses annually per respondent	Average burden hours per response	Estimated total annual burden hours
Summer Internship Program in Biomedical Research (SIP)	8,500	1	0.75	6,375.0
Biomedical Engineering Summer Internship Program (BESIP)	100	1	0.75	75.0
Post-baccalaureate Intramural Research Training Award	2,300	1	0.75	1,725.0
NIH Academy	550	1	0.75	412.5
Community College Summer Enrichment Program (CCSEP)	125	1	0.75	93.8
Technical Intramural Research Training Award	140	1	0.75	105.0
Graduate Partnerships Program (GPP)	600	1	0.75	450.0
Post-Doctorate Fellowship Program	2,050	1	0.75	1,537.5
National Graduate Student Research Festival (NGSRF)	825	1	0.75	618.8
Undergraduate Scholarship Program (UGSP)	300	1	0.75	225.0
Alumni Database	1,900	1	0.75	1,425.0