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

ESTIMATES OF HOUR BURDEN—Continued

Program	Estimated number of respondents	Estimated number of responses annually per respondent	Average burden hours per response	Estimated total annual burden hours
Recommendations for All Programs	35,705	1	0.25	8,926.3
Supplemental Documents for Application	14,540	1	0.75	10,905.0
Feedback Questions	53,095	1	0.25	13,273.8
Totals	120,730			46,147.5

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Patricia Wagner, Director of Admissions & Registrar, Office of Intramural Training & Education, National Institutes of Health, 2 Center Drive, Building 2/Room 2E06, Bethesda, Maryland 20892–0234, or call 240–476–3619 or e-mail your request, including your address to: *wagnerpa@od.nih.gov.*

DATES: *Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Date: July 15, 2010.

Michael M. Gottesman,

Deputy Director for Intramural Research, National Institutes of Health.

[FR Doc. 2010–17669 Filed 7–19–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0327]

International Conference on Harmonisation; Draft Recommendation for the Revision of the Permitted Daily Exposure for the Solvent Cumene According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft recommendation for the revision of the permitted daily exposure (PDE) for the solvent cumene according to the maintenance procedures for the guidance for industry entitled "Q3C: Impurities: Residual Solvents." The draft recommendation was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft recommendation before it begins work on the final recommendation, submit either electronic or written comments on the document by September 20, 2010.

ADDRESSES: Submit written requests for single copies of the draft recommendation to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft recommendation may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft recommendation.

Submit electronic comments on the draft recommendation to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0175.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with