

(OMB control number: 0938-0997); *Frequency*: On occasion; *Affected Public*: Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents*: 53,111; *Total Annual Responses*: 181,909,654; *Total Annual Hours*: 1,567,455. (For policy questions regarding this collection contact Matt Klischer at 410-786-7488.)

4. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection*: Health Insurance Common Claims Form and Supporting Regulations at 42 CFR part 424, Subpart C; *Use*: The Form CMS-1500 answers the needs of many health insurers. It is the basic form prescribed by CMS for the Medicare program for claims from physicians and suppliers. The Medicaid State Agencies, CHAMPUS/TriCare, Blue Cross/Blue Shield Plans, the Federal Employees Health Benefit Plan, and several private health plans also use it; it is the de facto standard "professional" claim form.

Medicare carriers use the data collected on the CMS-1500 and the CMS-1490S to determine the proper amount of reimbursement for Part B medical and other health services (as listed in section 1861(s) of the Social Security Act) provided by physicians and suppliers to beneficiaries. The CMS-1500 is submitted by physicians/suppliers for all Part B Medicare. Serving as a common claim form, the CMS-1500 can be used by other third-party payers (commercial and nonprofit health insurers) and other Federal programs (e.g., CHAMPUS/TriCare, Railroad Retirement Board (RRB), and Medicaid). However, as the CMS-1500 displays data items required for other third-party payers in addition to Medicare, the form is considered too complex for use by beneficiaries when they file their own claims. Therefore,

the CMS-1490S (Patient's Request for Medicare Payment) was explicitly developed for easy use by beneficiaries who file their own claims. The form can be obtained from any Social Security office or Medicare carrier. *Form Number*: CMS-1500(08/05), CMS-1490-S (OMB control number: 0938-0999) *Frequency*: On occasion; *Affected Public*: State, Local, or Tribal Governments, Private sector (Business or other-for-profit and Not-for-profit institutions); *Number of Respondents*: 1,448,346; *Total Annual Responses*: 988,005,045; *Total Annual Hours*: 21,418,336. (For policy questions regarding this collection contact Shannon Seales at 410-786-4089.)

Dated: October 13, 2015.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015-26390 Filed 10-15-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Native Language Preservation and Maintenance Grant Application Template Pilot (Funding Application Submission Tool (F.A.S.T. form))

OMB No.:

Description: The proposed F.A.S.T. form is intended to be used by applicants in the Administration for Native Americans' Native American Language Preservation and Maintenance grant competition in FY 2016. The F.A.S.T. form is proposed to be piloted as a consolidated and streamlined pre-

formatted electronic application form that is user-friendly and has an interactive interface providing structure and clarity for applicants. The proposed F.A.S.T. form is not intended to replace the Funding Opportunity Announcement (FOAs) which will still function as the full text of all funding opportunities for which applications are sought and considered by the Administration for Native Americans.

The proposed F.A.S.T. form will be used in a pilot capacity in just one Administration for Native Americans' discretionary program areas: Native American Language Preservation and Maintenance. All applicants applying for funding in that program area will be required to use the F.A.S.T. form during the pilot competition proposed for FY16 unless they request and receive approval to submit a paper application. By using the F.A.S.T. form no applicant will be required to provide any information beyond what is already required by the FOA. Additionally, free training and technical assistance will be available to all applicants on use of the F.A.S.T. form.

ANA intends to use the project proposals submitted via the F.A.S.T. form to make funding decisions for Native American Language Preservation and Maintenance grant awards made in the FY 2016 pilot year. In addition, ANA will solicit feedback from applicants and panel reviewers to obtain feedback on the results, outcomes, and their recommendations regarding the F.A.S.T. form as a user friendly method of applying for funding opportunities. If the pilot is successful in making it easier for applicants to apply, ANA will consider potentially expanding use of the F.A.S.T. form to all Administration for Native Americans' discretionary funding areas in subsequent years.

Respondents: 40.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
F.A.S.T. form	40	28	.50	14

Estimated Total Annual Burden Hours: 560.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447,

Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the

Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV,

Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015-26320 Filed 10-15-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-3474]

Draft Recommendations for the Permitted Daily Exposures for Two Solvents, Triethylamine and Methylisobutylketone, According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; International Conference on Harmonisation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of draft recommendations for a new permitted daily exposure (PDE) for the residual solvent triethylamine and a revised PDE for the residual solvent methylisobutylketone, according to the maintenance procedures for the guidance for industry entitled “Q3C Impurities: Residual Solvents.” The draft recommendations were prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The document is intended to recommend acceptable amounts for the listed residual solvents in pharmaceuticals for the safety of the patient.

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 the draft recommendations before it begins work on the final recommendations, submit either electronic or written comments on the document by December 15, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [http://](http://www.regulations.gov)

www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2015-D-3474 for “Draft Recommendations for the Permitted Daily Exposures for Two Solvents, Triethylamine and Methylisobutylketone, According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; International Conference on Harmonisation; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft recommendations to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft recommendations may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft recommendations.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Timothy J. McGovern, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6300, Silver Spring, MD 20993-0002, 240-402-0477.

Regarding the ICH: Michelle Limoli, CBER International Programs, Food and