DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–372(S), CMS–R–306, CMS–10180 and CMS–R–199]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations in 42 CFR 440.180 and 441.300–310; *Use:* CMS is asking the States to report financial and statistical information concerning the numbers of Medicaid beneficiaries receiving waiver services, the type of services provided and the costs of those services. The information is usually taken from State Medicaid agency data processing systems. This data is summarized and may be submitted to CMS through the 372 web-based form. The report is used by CMS to compare actual data in the approved waiver estimates and, in conjunction with the waiver compliance review reports, the information provided is compared to that in the Medicaid Statistical Information System (CMS–R–284, OCN 0938–0345) report and Federal financial participation claimed on a State's Quarterly Expenditure Report (CMS–64, OCN 0938–0067), to determine whether to continue the State's home and community-based services waiver. States' estimates of cost and utilization for renewal purposes are based upon the data compiled in the CMS Form 372(S) reports. There have been no changes to the PRA package that is associated with the 60-day notice that published on January 24, 2012 (77 FR 3477); *Form Number:* CMS–372(S) (OCN 0938–0272); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 49; *Total Annual Responses:* 305; *Total Annual Hours:* 13,115. (For policy questions regarding this collection contact Ralph Lollar at 410–786–0777. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Condition of Participation—Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals Under Age 21 and Supporting Regulations at 42 CFR 483.350–483.376; *Use:* Psychiatric Residential Treatment Facilities are required to report deaths, serious injuries and attempted suicides to the State Medicaid Agency and the Protection and Advocacy Organization. They are also required to provide residents the restraint and seclusion policy in writing, and to document in the residents' records all activities involving the use of restraint and seclusion. There have been no changes to the PRA package that is associated with the 60-day notice that published on January 13, 2012 (77 FR 2067); *Form Number:* CMS–R–306 (OCN 0938–0833); *Frequency:* Once and Occasionally; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 376; *Total Annual Responses:* 329,500; *Total Annual Hours:* 501,750. (For policy questions regarding this collection contact Jean Close at 410–786–2804 or Melissa Musotto at 410–786–6962. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Children's Health Insurance Program (CHIP) Report on Payables and Receivables; *Use:* Collection of CHIP data and the calculation of the CHIP Incurred But Not Reported (IBNR) estimate are pertinent to CMS' financial audit. The CFO auditors have reported the lack of an estimate for CHIP IBNR payables and receivables as a reportable condition in the FY 2005 audit of CMS's financial statements. It is essential that CMS collect the necessary data from State agencies in FY 2006, so that CMS continues to receive an unqualified audit opinion on its financial statements. Program expenditures for the CHIP have increased since its inception; as such, CHIP receivables and payables may materially impact the financial statements. The CHIP Report on Payables and Receivables will provide the information needed to calculate the CHIP IBNR; *Form Number:* CMS–10180 (OMB#: 0938–0988); Frequency: Reporting—Annually; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 392. (For policy questions regarding this collection contact Michele Myers at 410–786–7911. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Report on Payables and Receivables; *Use:* The Chief Financial Officers (CFO) Act of 1990, as amended by the Government Management Reform Act (GMRA) of 1994, requires government agencies to produce auditable financial statements. Because the Centers for Medicare & Medicaid Services (CMS) fulfills its mission through its contractors and the States, these entities are the primary source of information for the financial statements. There are three basic categories of data: Expenses, payables, and receivables. The CMS–64 is used to collect data on Medicaid expenses. The CMS–R–199 collects Medicaid payable and receivable accounting data from the States. *Form Number:* CMS–R–199 (OMB#: 0938–0697); *Frequency:* Reporting—Annually; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 336. (For policy questions regarding this collection contact Michele Myers at 410–786–7911. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *May 4, 2012.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov*.

Dated: March 28, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–8011 Filed 4–3–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0288]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#219) entitled ''Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51.''

This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to provide recommendations on how to use stability data generated in accordance with the principles detailed in the VICH guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products, GL3(R)'' to propose a retest period or shelf life in a registration application.

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 guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 4, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

FOR FURTHER INFORMATION CONTACT: Mai Huynh, Center for Veterinary Medicine, (HFV–142), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–276–8273, *Mai.huynh@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (#219) entitled, ''Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51.'' In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, the European Medicines Evaluation Agency, the European Federation of Animal Health, the Committee on Veterinary Medicinal Products, FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Statistical Evaluation of Stability Data

The VICH Steering Committee held a meeting on November 14, 2011, and agreed that the draft guidance document entitled ''Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51'' should be made available for public comment. This draft VICH guidance document is intended to provide recommendations on how to use stability data generated in accordance with the principles detailed in the VICH guidance entitled, ''Stability Testing of New Veterinary Drug Substances and Medicinal Products, GL3(R)'' to propose a retest period or shelf life in a registration application. This draft guidance describes when and how extrapolation can be considered when proposing a retest period for a drug substance or a shelf life for a veterinary medicinal product that extends beyond the period covered by available data from the stability study under the long-term storage condition.

This draft guidance addresses the evaluation of stability data that should be submitted in registration applications for new molecular entities and associated veterinary medicinal products. The draft guidance provides recommendations on establishing retest periods and shelf lives for drug substances and veterinary medicinal products intended for storage at or below ''room temperature.'' It covers stability studies using single- or multi-factor designs and full or reduced designs.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.