personnel, including requirements for average number and maximum number of cases per child protective service worker and supervisor.

11. The number of children reunited with their families or receiving family preservation services that, within five years, result in subsequent substantiated reports of child abuse or neglect, including the death of the child.

12. The number of children for whom individuals were appointed by the court to represent the best interests of such children and the average number of out of court contacts between such individuals and children.

13. The annual report containing the summary of activities of the citizen review panels of the state required by subsection (c)(6).

14. The number of children under the care of the state child protection system who are transferred into the custody of the state juvenile justice system.

15. The number of children referred to a child protective services system under subsection (b)(2)(B)(ii).

16. The number of children determined to be eligible for referral, and the number of children referred, under subsection (b)(2)(B)(xxi), to agencies providing early intervention services under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*).

The Children's Bureau proposes to continue collecting the NCANDS data through the two files of the Detailed Case Data Component, the Child File (the case-level component of NCANDS) and the Agency File (additional aggregate data, which cannot be collected at the case level). Technical assistance will be provided so that all states may provide the Child File and Agency File data to NCANDS. There are no proposed changes to the NCANDS data collection instruments. New fields were implemented during the previous OMB clearance cycle in support of the CAPTA Reauthorization Act of 2010 and to improve reporting on federal performance measures.

Respondents: State governments, the District of Columbia, and the Commonwealth of Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Detailed Case Data Component: Child File and Agency File	52	1	82	4,264

Estimated Total Annual Burden Hours: 4,264.

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. 2015–21625 Filed 8–31–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Collaboration Office Annual Report.

OMB No.: New Collection.

Description: The Office of Head Start within the Administration for Children and Families, United States Department of Health and Human Services, is proposing to collect information on the goals, work completed, and accomplishments of the Head Start Collaboration Offices (HSCOs). HSCOs facilitate partnerships between Head Start agencies and other state entities that provide services to benefit low income children and their families. HSCOs are awarded funds under Section 642B of the 2007 Head Start Act. The HSCO Annual Report is to be reported annually by all HSCO to ascertain progress and measurable results for the previous year. The results will also be used to populate the Collaboration Office profile Web pages on Early Childhood Learning & Knowledge Center (ECLKC) to promote the accomplishments of HSCO.

Respondents: Head Start State and National Collaboration Offices.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
HSCO Annual Report	54	1	4	216

Estimated Total Annual Burden Hours: 216.

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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–21619 Filed 8–31–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1177]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Electronic Exchange of Documents: Electronic File Format; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI #225) entitled ''Electronic Exchange of Documents: Electronic File Format'' (VICH GL53). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to cover the electronic file format specifications for individual documents and collections of multiple related documents that do not need subsequent modification during the regulatory procedure and are utilized for electronic exchange between industry and regulatory authorities in the context of regulatory approval of veterinary medicinal products.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Policy and Regulations Staff (HFV–6), 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 guidance document.

Submit electronic comments on the guidance 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: Scott Fontana, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0656, *scott.fontana@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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 Registration 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, European Medicines Evaluation Agency; European Federation of Animal Health, 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.

Six 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, one representative from the industry of Canada, one representative from the government of South Africa, and one representative from the industry of South Africa. 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. Guidance on Electronic Exchange of Documents: Electronic File Format

In the **Federal Register** of August 28, 2014 (79 FR 51342), FDA published a notice of availability for a draft guidance entitled ''Electronic Exchange of Documents: Electronic File Format'' (VICH GL53) giving interested persons until October 27, 2014, to comment on the draft guidance. FDA received two comments on the draft guidance and those comments, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated August 2014. The final guidance is a product of the Electronic File Format Expert Working Group of the VICH.

This VICH guidance document provides recommendations to industry regarding electronic file format specifications (*e.g.,* file format, file size, file security, and cross-referencing) for individual documents and collections of multiple related documents for the transfer of electronic regulatory information in support of applications for the approval of veterinary medicinal products. This guidance applies to communication or data exchanged as documents in the context of all regulatory procedures where regulatory authorities accept electronic transfer of such documents. This can include but is not limited to applications for initial marketing authorizations, related pre-submission or post-authorization