

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 1985D-0243 (formerly 85D-0243), 1984D-0115 (formerly 84D-0115), 1998D-0362 (formerly 98D-0362), 2003D-0061 (formerly 03D-0061), 2006D-0198, 1998D-0994 (formerly 98D-0994), 2003D-0571, 2000D-0186 (formerly 00D-0186), 1993D-0139 (formerly 93D-0139), 1996D-0010 (formerly 96D-0010), 1996D-0028 (formerly 96D-0028), 2001D-0361 (formerly 01D-0361), 2002D-0237 (formerly 02D-0237), 2002D-0231 (formerly 02D-0231), 1997D-0448 (formerly 97D-0448), 1998D-0374 (formerly 98D-0374), 2000D-1418 (formerly 00D-1418), 2005D-0021]

Guidance for Industry on Chemistry, Manufacturing, and Controls Information; Withdrawal and Revision of Seven Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal and revision.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of five and the revision of two guidances for industry, because some of the principles in these guidances are inconsistent with the agency's initiative, Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century (CGMP Initiative). Several of the guidances listed in this notice are cross-Center guidances relating to products regulated by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM).

FOR FURTHER INFORMATION CONTACT:

For products regulated by CDER: Jon Clark, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3550, Silver Spring, MD 20993-0002, 301-796-2020.

For products regulated by CBER: Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-1), Food and Drug Administration 1401 Rockville Pike, suite 200N Rockville, MD 20852-1448, 301-435-5681.

For products regulated by CVM: Dennis Bensley, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., MPN II, Rockville, MD 20855, 301-827-6956.

SUPPLEMENTARY INFORMATION: FDA is announcing the withdrawal of five and

the revision of two guidances for industry because of inconsistencies with the agency's CGMP Initiative, announced by FDA on August 21, 2002. FDA introduced the Initiative for a number of reasons: (1) To enhance the CGMP, (2) to focus our resources and regulatory attention on those aspects of manufacturing that pose the greatest risk to the quality of the product, (3) to ensure that our work does not impede innovation in manufacturing, and (4) to promote consistency in our regulatory approach. A report on the outcome of the initiative and the recommended steps for implementing a pharmaceutical quality regulatory system for the future can be found on the FDA Web site at http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm.

Many of FDA's previously published guidances relating to chemistry, manufacturing, and controls information were drafted prior to the CGMP Initiative. FDA has begun a review of its guidances for their consistency with the CGMP Initiative and is withdrawing five guidances and revising two guidances as listed below. Several of the guidances are cross-Center guidances.

CDER—Only Guidance for Withdrawal

- *Format and Content of the Chemistry, Manufacturing, and Controls Section of an Application*, February 1987.

CDER/CBER Guidances for Withdrawal

- *Submitting Documentation for the Stability of Human Drugs and Biologics*, February 1987.
- *Stability Testing of Drug Substances and Drug Products (Draft)*, June 1998.
- *Drug Product: Chemistry, Manufacturing, and Controls Information (Draft)*, January 2003.
- *Submission of Chemistry, Manufacturing and Controls Information for Synthetic Peptides*, November 1994.

CDER/CBER Guidances for Withdrawal; CVM Guidances for Revision

CDER and CBER are withdrawing the following two guidances from their Web sites:

- *BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation*, February 2001.
- *Drug Substance: Chemistry, Manufacturing, and Controls Information (draft)*, January 2004.

CVM made Level II revisions to the above two guidances to support their continued use in CVM for the approval of new animal drugs (e.g., removed references to human drug and biological products). The revised guidances are

available on <http://www.fda.gov/cvm>. CVM is committed to and supports the CGMP Initiative and may draft additional guidance that supports the CGMP Initiative as it relates to new animal drugs.

We will continue to review our guidances for their consistency with the CGMP Initiative and may withdraw or revise other guidances if they do not reflect our current thinking or to align them with the concepts of the CGMP Initiative, the Quality by Design Initiative, or Question-based Reviews. We also plan to develop new guidances to support these agency initiatives and to communicate guidance on submission of new drug applications and abbreviated new drug applications.

In the meantime, we recommend that the human drug pharmaceutical industry refer to the following International Conference on Harmonisation's (ICH) documents, which are available on FDA's Web sites, as alternate resources.

- *M4: Common Technical Document (CTD) for the Registration of Pharmaceuticals for Human Use (CTD)*, October 2001.
- *M4: The CTD—Quality*, August 2001.
- *Q1A(R2) Stability Testing of New Drug Substances and Products*, November 2003.
- *Q1B Photostability Testing of New Drug Substances and Products*, November 1996.
- *Q1C Stability Testing for New Dosage Forms*, May 1997.
- *Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products*, January 2003.
- *Q1E Evaluation of Stability Data*, June 2004.
- *Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV*, Revision 1, July 2004.
- *Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances*, December 2000.
- *Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products*, August 1999.
- *Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients*, August 2001.
- *Q8 Pharmaceutical Development (Draft)*, February 2005.

The above list is not intended to be exhaustive. If questions arise that are not covered in the ICH guidances, we recommend that pharmaceutical manufacturers contact the appropriate review division.

Dated: May 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection

AGENCY: Indian Health Service, HHS.

ACTION: Request for public comment: 60-day proposed information collection: Indian Health Service forms to implement the privacy rule (45 CFR parts 160 & 164).

SUMMARY: The Indian Health Service (IHS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the IHS is providing a 60-day advance opportunity for public comment on a proposed new collection of information to be submitted to the Office of Management and Budget for review.

Proposed Collection

Title: 0917-0030, "IHS Forms to Implement the Privacy Rule (45 CFR Parts 160 & 164)."

Type of Information Collection

Request: Extension, without revision, of currently approved information collection, 0917-0030, "IHS Forms to Implement the Privacy Rule (45 CFR Parts 160 & 164)".

Form Number(s): IHS-810, IHS-917, IHS-912-1, IHS-912-2, and IHS-913.

Need and Use of Information

Collection: This collection of information is made necessary by the Department of Health and Human Services Rule entitled "Standards for Privacy of Individually Identifiable Health Information" ("Privacy Rule") (45 CFR Parts 160 and 164). The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Information Portability and Accountability Act of 1996 and creates national standards to protect individual's personal health information and gives patients increased access to their medical records. 45 CFR 164.508, 522, 526 and 528 of the Rule require the collection of information to implement these protection standards and access requirements. The IHS will use the following data collection instruments to implement the information collection requirements contained in the Rule.

45 CFR 164.508: This provision requires covered entities to obtain or receive a valid authorization for its use or disclosure of protected health information for other than for treatment, payment and healthcare operations. Under the provision individuals may initiate a written authorization permitting covered entities to release their protected health information to entities of their choosing. The IHS-810 will be used to document an individual's authorization to use or disclose their protected health information.

45 CFR 164.522: Section 164.522(a)(1) requires a covered entity to permit individuals to request that the covered entity restrict the use and disclosure of their protected health information. The covered entity may or may not agree to the restriction. The form IHS-912-1 "Request for Restrictions(s)" will be used to document an individual's request for restriction of their protected health information and whether IHS agreed or disagreed with the restriction. Section 164.522(a)(2)(1) permits a covered entity to terminate its agreement to a restriction if the

individual agrees to or requests the termination in writing. The form IHS-912-2 "Request for Revocation of Restriction(s)" will be used to document the agency or individual request to terminate a formerly agreed to restriction regarding the use and disclosure of protected health information.

45 CFR 164.526: This provision requires covered entities to permit an individual to request that the covered entity amend protected health information. If the covered entity accepts the requested amendment, in whole or in part, the covered entity must inform the individual that the amendment is accepted and obtain the individual's identification of an agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared. If the covered entity denies the requested amendment, in whole or in part, the covered entity must provide the individual with a written denial. The form IHS-917 "Request for Correction/Amendment of Protected Health Information" will be used to document an individual's request to amend their protected health information and the agency's decision to accept or deny the request.

45 CFR 164.528: This provision requires covered entities to permit and individual to request that the covered entity provide an accounting of disclosures of protected health information made by the covered entity. The form IHS-913 "Request for an Accounting of Disclosures" will be used to document an individual's request for an Accounting of Disclosures of their protected health information and the agency's handling of the request.

Completed forms used in this collection of information are filed in the medical record.

Affected Public: Individuals and households.

Type of Respondents: Individuals.

Burden Hours: The table below provides the estimated burden hours for this information collection:

45 CFR section/IHS form	Number of respondents	Responses per respondent	Burden per response* (mins)	Total annual burden
164.506 IHS-810	500,000	1	20	166,667
164.522(a)(1) IHS-912-1	15,000	1	10	2,500
164.522(a)(2) IHS-912-2	5,000	1	10	833
164.526 IHS-917	7,500	1	15	1,875
164.528 IHS-913	15,000	1	10	2,500
Total Annual Burden		5		174,375

* For ease of understanding, burden hours are provided in actual minutes.