Dear Ms. Hayward:

I am responding to your request for reconsideration of Rhode Island State Plan Amendment (SPA) 02–009. Rhode Island submitted SPA 02–009 on September 28, 2002. In this amendment, Rhode Island proposed to provide coverage for targeted case management services to children age 21 and under who are receiving such services from the Rhode Island Department of Children, Youth, and Families.

The issues are whether the Centers for Medicare & Medicaid Services (CMS) properly found that SPA 02–009 is not consistent with Medicaid requirements because the proposed amendment: (1) duplicates coverage of services that are integral components of the Federal-state child welfare programs; and (2) fails to include a payment methodology for the proposed services and thereby does not comprehensively describe the plan and provide sufficient information to determine compliance with applicable statutory and regulatory requirements.

Under section 1902(a) of the Social Security Act (the Act), states must submit plans ''for medical assistance.'' Medical assistance is defined in section 1905(a) and 1905(a)(19) of the Act, and includes targeted case management authorized by section 1915(g)(2) of the Act. In authorizing coverage of case management services, Congress specifically indicated that coverage for case management services must not duplicate payments made to public agencies or private entities under other program authorities for the same purpose. Congress provided an exception, in section 8435 of the Technical and Miscellaneous Revenue Act of 1988, Public Law 100–647, when the state is required to provide such services under state law, or is or was otherwise paying for the services using non-Federal funds. The case management services proposed in this SPA, however, do not come within this exception because they are provided through a Federal-state program rather than a non-Federal program operated under state law. Specifically, case management comprises an integral part of the Federal child welfare program.

At issue is whether the activities proposed under this SPA as case management services were integral and inseparable to fulfillment of a state's responsibilities under title IV of the Act.

Under title IV–B of the Act, section 422(b)(2) expressly requires that states must ''provide for coordination between the services provided for children under the [state welfare] plan and the services and assistance provided under title XX, under the state program funded under part A (Title IV–A), under the state plan approved under part E (Title IV–E), and under other state programs having a relationship to the program under this subpart.'' The implementing regulations specify that services be organized and ''linked to a wide variety of supports and services which can be crucial to meeting families' and children's needs, for example, housing, substance abuse treatment, mental health, education, job training, child care, and informal support networks.'' (45 CFR section 1355.25(f))

In addition, 45 CFR 1357.10(c)(6) requires the Child and Family Services Plan, defined at 45 CFR section 1357.10(c) as ''the document, developed through joint planning, which describes the publicly-funded state child and family continuum,'' to include a broad spectrum of services, including foster care and child welfare services. Even though the activities in question may not always have been explicitly labeled as case management when performed under the State's title IV responsibilities, the State has provided no evidence that the activities are not the same.

Also at issue is whether SPA 02–009 comprehensively described the State program and contained sufficient information to determine whether it complied with Federal law. In the review process, CMS asked the State to submit an associated amendment to Attachment 4.19B of the State plan to describe the payment methodology that Rhode Island would use to make payments for the proposed services, in accordance with requirements set forth in section 1902(a)(30)(A) of the Act and 42 CFR 430.10. The State did not submit any payment methodology for the proposed services. CMS concluded that without any payment methodology for the proposed services, SPA 02–009 did not comprehensively describe the State's proposed Medicaid program, and did not contain sufficient information for CMS to determine that the proposed coverage was in compliance with applicable statutory and regulatory requirements.

I am scheduling a hearing on your request for reconsideration to be held on January 7, 2004, at 10 a.m., Government Center, JFK Federal Building, Viewstation 2320, Boston, Massachusetts 02203–0003. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. Ms. Scully-Hayes may be reached at (410) 786–2055.

Sincerely,
Thomas A. Scully

Section 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 430.18)
(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–29143 Filed 11–20–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0085]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Environmental Impact Considerations'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 2003 (68 FR 38063), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0322. The approval expires on September 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29068 Filed 11–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0084]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Electronic Records; Electronic Signatures'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 23, 2003 (68 FR 43531), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0303. The approval expires on May 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29071 Filed 11–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D–1598]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Suggested Documentation for Substantiating Whether Foods Have or Have Not Been Developed Using Bioengineering; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Withdrawal of notice.

SUMMARY: This document withdraws a Food and Drug Administration (FDA) notice that published in the **Federal Register** of October 31, 2003 (68 FR 62086).

DATES: This notice is withdrawn on November 21, 2003.

FOR FURTHER INFORMATION CONTACT: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: FDA published a notice in the **Federal Register** of October 31, 2003, informing interested parties that the proposed collection of information entitled ''Suggested Documentation for Substantiating Whether Foods Have or Have Not Been Developed Using Bioengineering'' had been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. However, this request for comments was issued prematurely. Thus, FDA is withdrawing the proposed collection of information at this time. FDA will reissue the request for comments when appropriate.

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29074 Filed 11–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0231 and 1993D–0139]

International Conference on Harmonisation; Stability Data Package for Registration Applications in Climatic Zones III and IV; Stability Testing of New Drug Substances and Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidances prepared under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The first is a guidance entitled ''Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV'' (the Q1F guidance). The second is a revised guidance entitled ''Q1A(R2) Stability Testing of New Drug Substances and Products'' (the Q1A guidance). The Q1F guidance, which is an annex to the Q1A guidance, defines an approach for broader use of the Q1A guidance for territories in climatic zones III and IV. The revised Q1A guidance incorporates relevant Q1F recommendations.

DATES: The guidance is effective November 21, 2003. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Submit written requests for single copies of the guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX: 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidances: Chi-wan Chen, Center for Drug Evaluation and Research (HFD–830), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2001; or Andrew Shrake, Center for Biologics Evaluation and Research (HFM–345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20052–1148, 301–402–4635.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonisation of regulatory requirements. FDA has participated in many meetings designed to enhance harmonisation 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.