using a product in ways that minimize risk; and (3) performance-linked access (PLA) systems that link product access to required laboratory testing or other documentation. The latter two categories have exhibited some success in minimizing risk, but may lead to disruptions in medical and pharmacy practice and unintended consequences, such as obstructing patient access to a product's benefits. It is the latter two tool categories (Reminder and PLA systems) that are the primary focus of this workshop. The following are a few of the products with Reminder or PLA systems: Isotretinoin (iPLEDGE), Thalidomide (STEPS), and Tysabri (TOUCH).

The workshop objectives are as follows: (1) Initiate constructive dialogue and information-sharing among regulators, researchers, and organizations and individuals affected by RiskMAP programs, particularly those using Reminder and PLA systems; (2) share key lessons learned about how to design and implement effective risk management systems to accommodate and promote quality healthcare and pharmacy practices; and (3) explore how tools being actively developed (such as electronic prescribing and integrated electronic health and medical records) and used to support high-quality, evidence-based practice may improve the development of RiskMAPs where Reminder and PLA systems are used or being considered for use.

Panel discussions as well as stakeholder presentations and testimony will focus on implementation strategies using Reminder and PLA systems to promote appropriate behavior changes to optimize patient outcomes, autonomy, access, cost, and logistics while reducing drug risks. We invite presentations that suggest ways to mitigate drug safety risks by improving healthcare system processes or emerging health information technologies. Examples might include linkages of electronic prescribing to laboratory or to patient electronic health records designed to improve the effectiveness of risk minimization efforts.

AHRQ and FDA are working together to refine the conference agenda and invite speakers. The agenda will be made available at *http://www.fda.gov/cder/meeting/riskMAPs.htm* not later than June 15, 2007. We are seeking broad participation by physicians, pharmacists, patients, health care quality and safety researchers, health systems officials, and payers of care. We anticipate issuing a summary of the conference findings, including a discussion of implications and next steps for further research or regulatory guidance development.

II. Comments

The agency is interested in hearing comments at the public workshop or receiving written comments (see **ADDRESSES**) on the following issues:

(1) Based on the diversity of experiences of different groups in implementing existing Reminder and PLA system RiskMAPs, what lessons have been learned that can be applied to future programs in the following areas:

- Minimizing risks;
- Maintaining provider and patient access to therapeutic choices;
- Minimizing burdens on the healthcare system;
- Being compatible with diverse technologies and settings of care;
- Avoiding adverse unintended consequences.

(2) How can healthcare information technology be used to assist quality prescribing, dispensing, and patient use to improve the effectiveness of RiskMAPs for drugs with risks where Reminder and PLA systems are used or likely to be used? How might HIT solutions be pursued and applied in light of the underdeveloped use of this technology in healthcare?

(3) How might professional organizations, third party payers of care, and others support the appropriate use of medications with processes or requirements such as those used with Reminder and PLA system RiskMAPs?

(4) Who are the relevant stakeholders in healthcare to involve in the design and choice of risk minimization tools? How can these stakeholders be best engaged in meaningful and productive partnerships and collaborations?

(5) Which activities and research should be pursued to develop a strong evidence base of healthcare system approaches, processes, and tools that support appropriate use of medications with safety problems where Reminder and PLA RiskMAPs are being used or considered for use?

(6) What partnerships will support evaluations of effectiveness of RiskMAPs or pilot interventions to minimize risk and promote appropriate medication prescribing, dispensing, and use?

(7) What future actions should AHRQ and FDA take to promote continued collaborations and contributions to the high-quality, appropriate use of medications with RiskMAPs?

III. Registration

The AHRQ Conference Center is a Federal facility with limited seating and security procedures for entrance. For these reasons, pre-registration is necessary for all attendees. Registration is available on a first-come basis. Individuals who wish to speak during the open public hearing must register on or before June 8, 2007; all other attendees must register on or before June 15, 2007. To register, contact *register@consolidatedsafety.com* or call 703–877–3345.

Ample time will be allowed during the scheduled agenda for attendees to ask questions of panelists. In addition, we strongly encourage written comments to the docket.

If you need special accommodations because of disability, please contact Lee Lemley (see **CONTACT FOR FURTHER INFORMATION**) at least 7 days before the workshop.

IV. Workshop Transcripts

The workshop will be transcribed. The transcript will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 30 days after the workshop.

Dated: May 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

Dated: May 16, 2007.

Carolyn Clancy,

Director, Agency for Healthcare Research and Quality, Department of Health and Human Services.

[FR Doc. 07–2574 Filed 5–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegation of Authority

Notice is hereby given that I have redelegated to the Director, Program Operations Division, Office of Head Start, the following authorities vested in me by the Assistant Secretary of Administration for Children and Families in the memoranda dated February 16, 2007.

(a) Authorities Delegated

1. Approve and disapprove refunding and supplemental funding applications for existing grantees, not including designated interim grantees.

2. Approve and disapprove collaboration grant applications authorized under 42 U.S.C. 9835.

3. Approve and disapprove contract proposals for award, not including proposals for national interim grantee contracts.

4. Approve and disapprove quality improvement plans (QIP) as required under 42 U.S.C. 9836A(d)(2)(B).

5. Conduct, as the responsible HHS official, informal meetings with current grantees or current or prospective delegate agencies as authorized by 45 CFR part 1303.11 and 1303.12.

6. Conduct, as the responsible HHS official, informal meetings authorized by 45 CFR part 1303.21 related to appeals by current or prospective delegate agencies.

7. Serve as the Approving Official to sign audit determination letters only where resolution does not involve a cost disallowance.

8. Approve and issue termination and suspension actions resulting from monitoring review reports approved and issued by the Regional Office.

(b) Limitations

1. The approval of grant applications requires concurrence of the appropriate Grants Officer.

2. The approval of contract proposals and awards are subject to the requirements of the Federal Acquisition Regulations and require consultation with the Director, Office of Head Start and the concurrence of the Contracting Officer.

3. The approval and issuance of terminations and suspensions resulting from monitoring review reports approved and issued by the Regional Office require the concurrence of the Director, Office of Head Start.

4. This redelegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

5. Any redelegation shall be in writing and prompt notification must be provided to all affected managers, supervisors, and other personnel, and requires the concurrence of the Deputy Assistant Secretary for Administration.

(c) Effective Date

This redelegation was effective on April 26, 2007.

(d) Effect on Existing Delegations

This redelegation of authority supersedes all previous delegations from the Director, Office of Head Start, on these subjects.

I hereby affirm and ratify any actions taken by the Director, Program Operations Division which, in effect, involved the exercise of these authorities prior to the effective date of this redelegation.

Dated: May 15, 2007.

Channell Wilkins,

Director, Office of Head Start.

[FR Doc. E7–9925 Filed 5–22–07; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegation of Authority

Notice is hereby given that I have redelegated to the Regional Program Managers, American Indian Alaska Native Program Branch Chief, and Migrant and Seasonal Program Branch Chief, Office of Head Start, the following authorities vested in me by the Director, Office of Head Start, in the memoranda dated April 26, 2007.

(a) Authorities Delegated

1. Approve and disapprove refunding and supplemental funding applications for existing grantees, not including designated interim grantees.

2. Approve and disapprove collaboration grant applications authorized under 42 U.S.C. 9835.

3. Approve and disapprove contract proposals for award, not including proposals for national interim grantee contracts.

4. Approve and disapprove quality improvement plans (QIP) as required under 42 U.S.C. 9836A(d)(2)(B).

5. Conduct, as the responsible HHS official, informal meetings with current grantees or current or prospective delegate agencies as authorized by 45 CFR 1303.11 and 1303.12.

6. Conduct, as the responsible HHS official, informal meetings authorized by 45 CFR part 1303.21 related to appeals by current or prospective delegate agencies.

7. Serve as the Approving Official to sign audit determination letters only where resolution does not involve a cost disallowance.

8. Approve and issue termination and suspension actions resulting from monitoring review reports approved and issued by the Regional Office.

(b) Limitations

1. The approval of grant applications requires concurrence of the appropriate Grants Officer.

2. The approval of contract proposals and awards are subject to the requirements of the Federal Acquisition Regulations and require consultation with the Director, Office of Head Start and the concurrence of the Contracting Officer.

3. The approval and issuance of terminations and suspensions resulting from monitoring review reports approved and issued by the Regional Office require the concurrence of the Director, Office of Head Start.

4. This redelegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

5. Any redelegation shall be in writing and prompt notification must be provided to all affected managers, supervisors, and other personnel, and requires the concurrence of the Deputy Assistant Secretary for Administration.

(c) Effective Date

This redelegation was effective on April 26, 2007.

(d) Effect on Existing Delegations

This redelegation of authority supersedes all previous delegations from the Director, Office of Head Start, on these subjects.

I hereby affirm and ratify any actions taken by any Regional Program Manager, the American Indian Alaska Native Program Branch Chief or the Migrant and Seasonal Program Branch Chief which, in effect, involved the exercise of these authorities prior to the effective date of this redelegation.

Dated: May 14, 2007.

Renee Perthuis,

Director, Program Operations Division.

[FR Doc. E7–9928 Filed 5–22–07; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0260]

Determination of Regulatory Review Period for Purposes of Patent Extension; ORENCIA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ORENCIA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent