Dated: March 24, 2011.
Marilyn Tavenner,
Principal Deputy Administrator and Chief
Operating Officer, Centers for Medicare &
Medicaid Services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Reunification Procedures for Unaccompanied Alien Children.
OMB No.: 0970–0278.

Description: Following the passage of the 2002 Homeland Security Act (Pub. L. 107–296), the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is charged with the care and placement of unaccompanied alien children in Federal custody, and implementing a policy for the release of these children, when appropriate, upon the request of suitable sponsors while awaiting immigration proceedings. In order for ORR to make determinations regarding the release of these children, the potential sponsors must meet certain conditions pursuant to section 462 of the Homeland Security Act and the Flores v. Reno Settlement Agreement No. CV85 4544–RJK (C.D. Cal. 1997). The proposed information collection requests information to be utilized by ORR for determining the suitability of a sponsor/respondent for the release of a minor from ORR custody. The proposed instruments are the Sponsors Agreement to Conditions of Release, Reunification Packet, and the Authorization for Reunification Packet, and the Authorization for Release of Information.

Respondents: Sponsors requesting release of unaccompanied alien.

ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verification of Release (UAC)</td>
<td>4,595</td>
<td>1</td>
<td>1,148.75</td>
</tr>
<tr>
<td>Authorization for Release of Information (Sponsor)</td>
<td>4,595</td>
<td>1</td>
<td>1,148.75</td>
</tr>
<tr>
<td>Family Reunification Packet (Sponsor)</td>
<td>4,595</td>
<td>1</td>
<td>4,595</td>
</tr>
<tr>
<td>Sponsors Agreement to Conditions of Release (Sponsor)</td>
<td>4,595</td>
<td>1</td>
<td>1,148.75</td>
</tr>
<tr>
<td>Verification of Release (Case Worker)</td>
<td>4,595</td>
<td>0.25</td>
<td>1,148.75</td>
</tr>
<tr>
<td>Authorization for Release of Information (Case Worker)</td>
<td>4,595</td>
<td>0.25</td>
<td>4,595</td>
</tr>
<tr>
<td>Family Reunification Packet (Case Worker)</td>
<td>4,595</td>
<td>1</td>
<td>1,148.75</td>
</tr>
<tr>
<td>Sponsors Agreement to conditions of Release (Case Worker)</td>
<td>4,595</td>
<td>0.25</td>
<td>4,595</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden Hours: 16,082.50.

Additional Information:
Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 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. E-mail 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, E-mail: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Dated: March 29, 2011.
Robert Sargis,
Reports Clearance Officer.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2010–N–0474]

Maja S. Ruetschi: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Maja S. Ruetschi, MD for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on findings that Dr. Ruetschi was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs.

Dr. Ruetschi was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Ruetschi failed to respond. Dr. Ruetschi’s failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective April 4, 2011.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–
II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Maja S. Ruetschi has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act, and that the type of conduct that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Dr. Ruetschi is debarred for 5 years from providing services in any capacity to a person that has an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Ruetschi, in any capacity during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Ruetschi provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act).

III. Supplemental Information

As a result of the foregoing finding, Dr. Ruetschi is debarred for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)), that Dr. Ruetschi was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Dr. Ruetschi an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Ruetschi failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

IV. Request for Hearing


SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Marilyn Mehlmauer, MD for 4 years from providing services in any capacity to a person who has an approved or pending drug product application. FDA bases this order on findings that Dr. Mehlmauer was convicted of a misdemeanor under Federal Law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. Dr. Mehlmauer was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Mehlmauer failed to respond. Dr. Mehlmauer’s failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective April 4, 2011.

ADDRESS: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration,