DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Required Elements for Voluntary Establishment of Paternity Affidavits.
OMB No.: 0970–0171.
Description: Section 466(a)(5)(C) of the Social Security Act requires States to pass laws ensuring a simple civil process for voluntarily acknowledging paternity under which the State must provide that the mother and putative father must be given notice, orally and in writing, of the benefits and legal responsibilities and consequences of acknowledging paternity. The information is to be used by hospitals, birth record agencies, and other entities participating in the voluntary paternity establishment program.

Respondents: State and Tribal IV–D birth record agencies.

ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>862,043</td>
<td>Variable</td>
<td>.166</td>
<td>143,099</td>
</tr>
</tbody>
</table>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0058]

Hospira, Inc. et al.; Withdrawal of Approval of 76 New Drug Applications and 60 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of March 4, 2005 (70 FR 10651). The document announced the withdrawal of approval of 76 new drug applications (NDAs) and 60 abbreviated new drug applications (ANDAs). The document inadvertently withdrew approval of ANDA 76–214 for Sotalol Hydrochloride Tablets, 80 milligrams (mg), 120 mg, and 160 mg, held by TorPharm, c/o Apotex Corp., 616 Heathrow Dr., Lincolnshire, IL 60069. FDA confirms that approval of ANDA 76–214 is still in effect.

EFFECTIVE DATE: April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In FR Doc. 05–4158, appearing on page 10651 in the Federal Register of Friday, March 4, 2005, the following correction is made:

1. On page 10656, in the table, the entry for ANDA 76–214 is removed.

Dated: April 14, 2005.

Steven Galson, Acting Director.
Center for Drug Evaluation and Research.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The Eighth Annual FDA–Orange County Regulatory Affairs Educational Conference; “Reality of Regulatory Affairs”

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing its eighth annual educational conference cosponsored with the Orange County Regulatory Affairs Discussion Group (OCR). The conference is intended to provide the drug, device, and biologics industries with an opportunity to interact with FDA reviewers and compliance officers from the centers and district offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive question and answer and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.