Leroy A. Richardson, 
Chief, Information Collection Review Office, 
Office of Scientific Integrity, Office of the 
Associate Director for Science, Office of the 
Director, Centers for Disease Control and 
Prevention. 
[FR Doc. 2015–12809 Filed 5–27–15; 8:45 am] 
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND 
HUMAN SERVICES

Administration for Children and 
Families

Proposed Information Collection 
Activity; Comment Request

Proposed Projects

Title: Head Start Facilities 
Construction, Purchase and Major 
Renovation.

OMB No.: 0970–0193. 

Description: The Office of Head Start 
within the Administration for 
Children and Families, United States 
Department of Health and Human 
Services, is proposing to renew authority to collect 
information on funding for the 
purchase, construction or renovation of 
facilities. All information is collected 
electronically through the Head Start 
Enterprise System (HSES). The 
information required is in conformance with 
Section 644(f) and (g) of the Act. 
Federal funding officials use the 
information to determine that the 
proposed purchase has resulted in 
savings when compared to the costs that 
would be incurred to acquire the use of 
an alternative facility, or that the lack of 
alternative facilities will prevent, or 
would have prevented, the operation of the 
program. The rule further describes 
the assurances which are necessary to 
protect the Federal interest in real 
property and the conditions under 
which federal interest may be 
subordinated and protected when 
grantees make use of debt instruments 
when purchasing facilities. The 
information is used by funding officials 
to determine if grantee's arrangements 
adequately conform to other applicable 
statutes which apply to the expenditure 
of public funds for the purchase of real 
property.

Respondents: Head Start and Early 
Head Start program grant recipients.

ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instruments</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>Administrative Requirements</td>
<td>225</td>
<td>1</td>
<td>41</td>
<td>9225</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden Hours: 9225.

Cost per respondent is $40 estimated at 2 hours × $20.00 per hour.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L’Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis, 
Reports Clearance Officer. 
[FR Doc. 2015–12924 Filed 5–27–15; 8:45 am] 
BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND 
HUMAN SERVICES

Food and Drug Administration 

M7 Assessment and Control of DNA 
Reactive (Mutagenic) Impurities in 
Pharmaceuticals to Limit Potential 
Carcinogenic Risk; International 
Conference on Harmonisation; 
Guidance for Industry; Availability 

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled “M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.” The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical
I. Background

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

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the Federal Register of April 15, 2013 (72 FR 22269), FDA published a notice announcing the availability of a draft guidance entitled “M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.” The notice gave interested persons an opportunity to submit comments by June 14, 2013. Changes made to the guidance took into consideration written comments received. Minor editorial changes were made to improve clarity.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in June 2014.

The guidance provides guidance on the regulation of genotoxic impurities in new drug substances and drug products. This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access


Dated: May 20, 2015.

Leslie Kux,
Associate Commissioner for Policy.