

FDA selected “individual consumer” comments for non-posting because of previous concerns raised by individuals and the conclusion that such commenters may not be as familiar with the regulatory process and the public nature of dockets as are other entities, such as regulated industry.

In recent years, FDA has occasionally made exceptions to this non-posting practice, typically using the COMMENTS section in a particular **Federal Register** document to alert the public that all comments were subject to public posting. FDA **Federal Register** documents, requesting or providing for the submission of comments, published subsequent to this notice will contain new instructions and information concerning the posting of comments submitted to that particular docket.

This change fulfills a recommendation from the 2010 FDA Transparency Initiative<sup>2</sup> and aligns with a 2013 recommendation from the Administrative Conference of the United States that “[a]gencies should manage their public rulemaking dockets to achieve maximum public disclosure” consistent with legal limitations and other claims of privilege.<sup>3</sup> It also furthers an objective in Executive Order 13563,<sup>4</sup> which directs Agencies to base their regulations on “public participation and an open exchange of ideas.”

## II. Consumer Comments and Confidential Information

The commenter is solely responsible for ensuring that the submitted comment does not include any confidential information that the commenter or a third party may not wish to be posted, such as private medical information, the commenter’s or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. If a name, contact information, or other information that identifies the commenter is included in the body of the submitted comment, that information will be posted on <http://www.regulations.gov>. FDA will post comments, as well as any attachments submitted electronically, on <http://www.regulations.gov>, along with the State/Province and country (if

provided), the name of the commenter’s representative (if any), and the category selected to identify the commenter (e.g., individual, consumer, academic, industry).

The Agency expects that only in exceptional instances would a comment need to include private, personal, or confidential information. If a comment is submitted with confidential information that the commenter does not wish to be made available to the public, the comment would be submitted as a written/paper submission and in the manner detailed in the applicable **Federal Register** document. For written/paper comments submitted containing confidential information, FDA will post the redacted/blacked out version of the comment including any attachments submitted by the commenter. The unredacted copy will not be posted, assuming the commenter follows the instructions in the applicable **Federal Register** document. Any information marked as confidential will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law.

FDA will include new information and standard instructions for submitting comments in all **Federal Register** documents requesting or providing for the submission of comments. The instructions will explain how to submit comments to the docket on that particular document via electronic means and also will explain the process for submission of comments, in written/paper format, that the commenter wishes to mark as confidential.

## III. Date of Implementation

All comments submitted electronically through <http://www.regulations.gov> to any FDA docket, existing or new, after October 15, 2015, will be posted to the applicable docket and publicly viewable on <http://www.regulations.gov>. All comments submitted by mail or delivery to the Division of Dockets Management in written/paper format to any FDA docket, existing or new, after October 15, 2015, will be posted to the applicable docket and publicly viewable on <http://www.regulations.gov> unless submitted under the following conditions: (1) The written/paper submission is marked as confidential, and (2) the submitter provides an unredacted and a redacted version; the redacted version must have the information claimed as confidential redacted/blacked out. If submitted under these conditions, only the redacted/blacked out written/paper submission will be posted publicly on

<http://www.regulations.gov>, except as otherwise provided by § 10.20 or other law.

Dated: September 14, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: HHS–OS–0990–0279–30D]

### Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990–0279, scheduled to expire on September 30, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before October 19, 2015.

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690–6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the OMB control number 0990–0279 and document identifier HHS–OS–30D for reference.

*Information Collection Request Title:* Institutional Review Board Form—OMB No. 0990–0279, Assistant Secretary for Health, Office for Human Research Protections.

*Abstract:* Section 491(a) of Public Law 99–158 states that the Secretary of HHS shall by regulation require that each entity applying for HHS support (e.g., a grant, contract, or cooperative

<sup>2</sup> “FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration,” May 2010, available at [www.fda.gov/AboutFDA/Transparency/PublicDisclosure](http://www.fda.gov/AboutFDA/Transparency/PublicDisclosure) (p. 4).

<sup>3</sup> Recommendation No. 2013–4, available at <http://www.acus.gov/recommendation/administrative-record-informal-rulemaking>.

<sup>4</sup> Executive Order 13563, available at <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

agreement) to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research in order to ensure protection of the rights and welfare of the human research subjects. IRBs are boards, committees, or groups formally designated by an entity to review, approve, and have continuing oversight of research involving human subjects.

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990-0279, Institutional Review Board (IRB) Registration Form.

This form was modified in 2009 to be consistent with IRB registration requirements, 45 CFR 46, subpart E and 21 CFR 56.106 that were adopted in July 2009 OHRP and FDA, respectively.

*Need and Proposed Use of the Information:* The information collected through the Institutional Review Board registration collection requirements is the minimum necessary to satisfy the registration requirements of Section 491(a) of the Public Health Service Act, 45 CFR part 46, subpart E and 21 CFR 56.106.

*Likely Respondents:* Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's regulations, IRBs in the United

States that review clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and, IRBs in the United States that review clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

*Burden Statement:* The burden estimates for the IRB registration form include those approved by OMB in March 2015 under Control Number 0990-0263, the Assurance Identification/IRB Certification/Declaration of Exemption form (former Optional Form 310). Those burden estimates are not included as part of the burden estimate presented below.

ESTIMATED ANNUALIZED BURDEN TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration 0990-0279 .....	5,900	2	1	11,800
New Registration .....	500	2	1	1,000
Total .....				12,800

**Darius Taylor,**  
*Information Collection Clearance Officer.*  
 [FR Doc. 2015-23453 Filed 9-17-15; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Bethesda Campus Chilled Water System Improvements Record of Decision**

**SUMMARY:** The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Environmental Impact Statement (FEIS) and a thorough consideration of the public comments on the Draft EIS, to implement the Proposed Action, referred to as the Proposed Action in the Final EIS. This action is to install a Thermal Energy Storage System and an Industrial Water Storage System to provide sufficient storage capacity to meet two days of chilled water demand and two days of industrial water demand should an outside disturbance interrupt the water supply.

**FOR FURTHER INFORMATION CONTACT:**  
 Valerie Nottingham, Deputy Director,  
 DEP, ORF, NIH, Building 13, Room 2S11, 9000 Rockville Pike, Bethesda, MD 20892, Phone 301-496-7775,

*nihnepa@mail.nih.gov. Responsible Official:* Daniel G. Wheeland, Director, Office of Research Facilities (ORF) Development and Operations, NIH.

**SUPPLEMENTARY INFORMATION:**

**Decision**

After careful review of the environmental consequences in the Final Environmental Impact Statement for the Chilled Water System Improvements, National Institutes of Health, and consideration of public comment throughout the NEPA process, the NIH has decided to implement the Proposed Action described below as the Selected Alternative.

**Selected Alternative**

The Selected Alternative would implement chilled water system improvements that would enable the NIH to adequately accomplish the project goals. This would include sufficient storage capacity to meet two days of chilled water demand and two days of industrial water demand should an outside disturbance interrupt the normal supply of water by the WSSC.

Elements of the Chilled Water System Improvements project that the NIH would implement under the Proposed Action include the following:

*Thermal Energy Storage System*

This system would be located at the Building 34 site and would store up to

approximately nine million gallons of chilled water. Components of the system would include a storage tank, at or partially below-grade, with a footprint of approximately 12,000 SF; a pump house building with a footprint of approximately 5,000 SF or less; support equipment, such as pumps, valves, piping, controls, and an emergency generator; and security fencing, lighting, and other site improvements. The NIH would use this system to meet chilled water demands within the Campus.

*Industrial Water Storage System*

This system would be located at the Parking Lot 41 site and would store up to approximately five million gallons of industrial water. Industrial water is water that the CUP utilizes to generate steam or chilled water. Components of the system would include a storage tank, partially below-grade; a pump house building with a footprint of approximately 5,000 SF; support equipment, such as pumps, valves, variable frequency drivers, electrical equipment, switchgear, piping, controls, instrumentation, and an emergency generator; and security fencing, lighting, and other site improvements. The NIH would use this system to ensure an adequate supply of water to the chillers.

*Other Supporting Infrastructure*

The Thermal Energy Storage System and the Industrial Water Storage System