

divestitures to Watson is not acceptable, the parties must unwind the sale and divest the Products within six months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six months, the Commission may appoint a trustee to divest the Product assets.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Perrigo and Paddock to provide transitional services to enable Watson to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Perrigo and Paddock. In addition, the parties must supply Watson with the Products pursuant to a supply agreement while they transfer the manufacturing technology to a third-party manufacturer of Watson's choice.

The Consent Agreement also preserves competition in the market for testosterone gel by prohibiting the parties from: (1) receiving any payments that accrue after the initial term of the backup supply agreement aside from those for manufacturing the product; and (2) entering into any anticompetitive pay-for-delay arrangements with Abbott regarding the testosterone gel product.

The Commission has appointed F. William Rahe of Quantic Regulatory Services, LLC ("Quantic") as the Interim Monitor to oversee the asset transfer and to ensure Perrigo and Paddock's compliance with the provisions of the proposed Consent Agreement. Mr. Rahe is a senior consultant at Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires the parties to file reports with the Commission periodically until the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Richard C. Donohue,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-New; 60-day Notice]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA) of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Sherette.funncoleman@hhs.gov, or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

Proposed Project: Descriptive information of solutions provided to the Federal government in response to Challenge and Competition solicitations posted on *Challenge.gov*.— OMB No. 0990-New-Immediate Office of the Secretary.

Abstract: This request is to seek generic clearance for the collection of routine information requested of responders to solicitations the Federal government makes during the issuance of challenges and competitions posted

on the General Service Administration (GSA)'s *Challenge.gov* Web site. Since passage of the America COMPETES Act of 2011, challenge competitions are increasingly being used by Federal agencies to solve complex problems and obtain innovative solutions. In this role, the Federal government places a description of a problem and parameters of the solution on the *Challenge.gov* Web site. The solutions are evaluated by the submitting agency and typically prizes (monetary and non-monetary) are awarded to the winning entries.

This clearance applies to challenges posted on *Challenge.gov* which uses a common platform for the solicitation of challenges from the public. Each agency designs the criteria for its solicitations based on the goals of the challenge and the specific needs of the agency. There is no standard submission format for solution providers to follow.

We anticipate that approximately 100 challenges would be issued each year by HHS, with an average of 15 submissions to each challenge solicitation. It is expected that other federal agencies will issue a similar number of challenges. There is no set schedule for the issuance of challenges; they are developed and issued on an "as needs" basis in response to issues the federal agency wishes to solve. The respondents to the challenges, who are participating voluntarily, are unlikely to reply to more than one or several of the challenges.

Although in recent memoranda the GSA and Office of Management and Budget (OMB) described circumstances whereby OMB approval of a PRA request is not needed, program officials at HHS have identified several sets of information that will typically need to be requested of solution providers to enable the solutions to be adequately evaluated by the federal agency issuing the challenge. These requests for additional information have been suggested to require a PRA review as they represent structured data requests.

There are three types of additional data that will be routinely requested by the federal agencies. These include the following:

Title of the submission. Due to the nature of the submission and evaluation processes, it is important that a title be requested and submitted for each submission in order to ensure the solution is correctly identified with its provider.

Identification of data resources. In many cases, the solution to a problem will require the solution provider to use data resources. Often, the nature of the data sets will be derived from Federal data resources, such as *data.gov*. Evaluations of solutions will often depend on the understanding of the selection of the data resource(s) used in the solution.

Description of methodology. For effective judging and evaluation, a description of the development methods for the solution to the challenge will be requested. For instance, a

prize may be awarded to the solution of a challenge to develop an algorithm that enables reliable prediction of a certain event. A responder could submit the correct

algorithm, but without the methodology, the evaluation process could not be adequately performed.

ESTIMATED ANNUALIZED BURDEN TABLE

| Forms | Type of respondent | No. of respondents | No. of responses per respondent | Average burden (in hours) per response | Total burden hours |
|----------------------------|--|--------------------|---------------------------------|--|--------------------|
| Challenge Template A | Individuals or Households | 500 | 1 | 10/60 | 83.3 |
| Challenge Template A | Organizations | 500 | 1 | 10/60 | 83.3 |
| Challenge Template A | Businesses | 500 | 1 | 10/60 | 83.3 |
| Challenge Template A | State, territory, tribal or local governments. | 30 | 1 | 10/60 | 5 |
| Challenge Template A | Federal government | 30 | 1 | 10/60 | 5 |
| Total | | 1,560 | | | 255.9 |

Mary Forbes,

*Paperwork Reduction Act Clearance Officer,
Office of the Secretary.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Calculation of Annual Federal Medical Assistance Percentages for Indian Tribes for Use in the Title IV-E Foster Care, Adoption Assistance, and Kinship Guardianship Assistance Programs

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice.

SUMMARY: This notice finalizes the methodology that will be used to calculate reimbursement rates applicable to fiscal years 2010 and beyond for assistance payments under the tribal Foster Care, Adoption Assistance and Guardianship Assistance Programs authorized by title IV-E of the Social Security Act. A Notice with Comment Period on this topic was previously published on October 8, 2010.

DATES: *Effective Date.* The methodology described in this Notice is effective upon publication.

A. Background

The Fostering Connections to Success and Increasing Adoptions Act of 2008 ("Fostering Connections Act," Pub. L. 110-351), authorizes Indian tribes, tribal organizations and tribal consortia to receive funding directly for Foster Care, Adoption Assistance, and Kinship Guardianship Assistance Programs under title IV-E of the Social Security Act (42 U.S.C. 679c). Such direct funding was authorized to begin in fiscal year (FY) 2010 for Indian tribes, tribal organizations or tribal consortia

with approved title IV-E plans, or eligible Indian tribes may submit plans to operate such programs at any time in the future. Indian tribes not operating their own programs may receive title IV-E funds through cooperative agreements or contracts with the States within which they are located. The methodology described in this notice is also applicable in calculating reimbursement rates under such agreements beginning in FY 2010.

The Federal share of assistance payments for the Title IV-E Foster Care, Adoption Assistance and Kinship Guardianship Assistance Programs is calculated using the Federal Medical Assistance Percentage (FMAP), a match rate calculated annually for each State by the Department of Health and Human Services (HHS) according to a formula specified in statute (section 1905(b) of the Social Security Act, 42 U.S.C. 1396d(b)). The FMAP formula involves comparing the State's average per capita income over a three year period with the average per capita income of the U.S. as a whole for the same three year period, and results in FMAP rates that vary between statutory minimum and maximum levels of 50 and 83 percent. The formula produces higher Federal matching rates for jurisdictions with lower per capita incomes relative to the U.S. as a whole.

Indian tribes previously have not been authorized to directly administer Federal programs that use FMAPs and therefore tribal FMAPs have not previously been calculated. However, the Fostering Connections Act requires HHS to establish FMAP rates for Indian tribes, tribal organizations, or tribal consortia (Pub. L. 110-351, section 301(d); 42 U.S.C. 679c(d)). The Act further specifies that each Tribe's annual FMAP shall be based on the per capita income of the service population of the Indian tribe, tribal organization,

or tribal consortium. However, no tribal FMAP shall be lower than the FMAP of any State in which the Indian tribe, tribal organization, or tribal consortium is located.

The FMAP rates calculated using the methodology described here will be used for Indian tribes' title IV-E Foster Care, Adoption Assistance, and Kinship Guardianship Assistance programs whether they are administered directly by the Indian tribe or through an agreement or contract with a title IV-E State agency per sections 474(a)(1) and (2) of the Social Security Act, 42 U.S.C. 674(a)(1) and (2). Thus, a State may also claim reimbursement for title IV-E allowable assistance payments made on behalf of tribal children served through agreements or contracts with Indian tribes at the higher of the FMAP rate applicable to the State or the FMAP rate for the involved Indian tribe.

B. Outreach Regarding the October 8, 2010, Federal Register Notice and Comments Received

On October 8, 2010, HHS published a **Federal Register** Notice requesting comments on its proposed methodology for calculating FMAP for Indian tribes. A 60-day comment period was provided. HHS mailed copies of the Notice to tribal chairman of all federally recognized Indian tribes and posted the Notice to several electronic listserves operated by the Department's Administration for Children and Families that are most relevant to tribal child welfare programs. Each of the letters and postings provided dates and call-in instructions for four conference calls that were to be held to describe the content of the Notice and answer any questions Tribes may have had about it. These calls were held on November 3, 4, 9 and 10, 2010.

A single set of written comments was received on the content of the **Federal**