

drug. Rather, generic suppliers compete only against each other. In generic pharmaceutical product markets, price generally decreases as the number of generic competitors increases. The United States is the relevant geographic market for generic drugs because the U.S. Food and Drug Administration ("FDA") must approve them for sale within the United States.

There are currently only three suppliers of each dosage strength of generic minocycline tablets in the United States: Ranbaxy, Dr. Reddy's Laboratories Ltd., and Par Pharmaceutical Companies, Inc. Sun is one of only a limited number of firms likely to enter the generic minocycline tablets markets in the near future. Sun's acquisition of Ranbaxy would therefore deprive consumers of the increased competition and likely price reductions that would have occurred as a result of Sun's independent entry.

II. Entry

Entry into the markets for generic minocycline tablets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

III. Effects

The Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred when Sun's generic minocycline tablets entered the markets. Market participants characterize generic minocycline tablets as commodities, and each market as one in which the number of generic suppliers has a direct impact on pricing. Customers and competitors have confirmed that the price of generic pharmaceutical products decreases with new entry even after several other suppliers have entered the market. Further, customers generally believe that having at least four suppliers in each generic pharmaceutical market produces more competitive prices than if fewer suppliers are available to them.

The Proposed Acquisition would eliminate significant future competition between Sun and Ranbaxy. The evidence shows that anticompetitive effects are likely to result from the Proposed Acquisition due to the elimination of an additional independent competitor in the markets for generic minocycline tablets, which would have allowed customers to

negotiate lower prices. Thus, absent a remedy, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for generic minocycline tablets.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant markets. Pursuant to the Consent Agreement and the Order, the parties are required to divest all of Ranbaxy's rights and assets to generic minocycline tablets to Torrent. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Torrent is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Torrent and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The Order requires that Ranbaxy transfer to Torrent all confidential business information and requires that Sun and Ranbaxy take all actions that are necessary to maintain the full viability and marketing of the generic minocycline tablets until Torrent commences the distribution, marketing, and sale of the products.

The proposed Order also requires the parties to divest Ranbaxy's generic minocycline hydrochloride 50 mg, 75 mg, and 100 mg capsules ("minocycline capsules") to Torrent to ensure that Torrent achieves regulatory approval to qualify a new API supplier for its minocycline tablets as quickly as Ranbaxy would have. Torrent will be able to establish the current API supplier of the minocycline capsules as the API supplier for its minocycline tablets through a less time-intensive regulatory process if Torrent controls both products and uses the same API supplier for both. Moreover, the proposed Order requires Sun and Ranbaxy to manufacture and supply generic minocycline tablets and capsules to Torrent following the divestiture to allow Torrent to enter the

markets while it validates its manufacturing process and seeks the necessary FDA approvals.

The Commission will appoint Frank Civile to act as an interim monitor to assure that Sun and Ranbaxy expeditiously comply with all of their obligations and perform all of their responsibilities pursuant to the Consent Agreement. In order to ensure that the Commission remains informed about the status of the transfer of rights and assets, the Consent Agreement requires Sun and Ranbaxy to file reports with the interim monitor who will report in writing to the Commission concerning performance by the parties of their obligations under the Consent Agreement.

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.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS-OS-0990-New-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 a new collection. 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 March 9, 2015.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

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

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS-OS-0990-New-30D for reference.

Information Collection Request Title: Evaluation of the National Training on Trauma-Informed Care (TIC).

Abstract: The HHS OWH is requesting OMB approval to conduct a new, one time outcome evaluation of the *National Training Initiative on Trauma-Informed Care (TIC) for Community-Based Providers From Diverse Service Systems*

training curriculum. Policymakers and providers in many service sectors recognize the central role of trauma in causing or complicating physical and behavioral health conditions and the critical need for trauma-informed care (TIC) systems. The proposed evaluation will capture both knowledge gained and implementation impact achieved as a result of the TIC training and TA. Analyses and findings will be used to further refine the TIC curriculum and training approach, and can help inform OWH and HHS in future policymaking efforts. Information collected will also help researchers and practitioners better understand the impact of adopting a trauma-informed approach on and the

quality of care provided by community-based providers.

Likely respondents:

Site Visits

Site visits are designed to capture both the knowledge gained by training participants and the implementation impact achieved in their organizations as a result of the OWH TIC training and technical assistance.

Online Survey

The goal of the online survey is to assess the impact of the training on participants' skills acquired in, knowledge about, and values and beliefs surrounding trauma-informed care.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Online Survey	Leadership and Line/Other Frontline Staff.	300	1	25/60	125
Site Visits	Leadership and Line/Other Frontline Staff.	144	1	40/60	96
Total					221

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2015-02313 Filed 2-5-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on the Draft National Adult Immunization Plan

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (Pub. L. 99-660) (§ 2105) (*42 U.S. Code 300aa-5 (PDF—78 KB)*). Its purpose is to advise and make recommendations to the Director of the National Vaccine Program on matters related to program responsibilities. The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services (HHS) as the Director of the National Vaccine Program. The National Vaccine Program Office (NVPO) is

located within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary, U.S. Department of Health and Human Services (HHS). NVPO provides leadership and fosters collaboration among the various federal agencies involved in vaccine and immunization activities. The NVPO also supports the National Vaccine Advisory Committee (NVAC). The NVAC advises and makes recommendations to the ASH in his capacity as the Director of National Vaccine Program on matters related to vaccine program responsibilities.

Adult vaccination rates remain low in the United States, and significant racial and ethnic disparities exist. In 2011, NVAC recommended the development of a strategic plan with the goal of improving adult immunization.

Through an environmental scan of past reports issued by vaccine stakeholders, a survey, several focus groups, and in-depth interviews with subject matter experts, and in consultation with federal partners, NVPO has developed the draft National Adult Immunization Plan (NAIP). The NAIP details background on the immunization landscape and provides a strategic plan for federal and nonfederal stakeholders.

NVPO is soliciting public comment on the draft NAIP from a variety of

stakeholders, including the general public, for consideration as they develop their final report to the Secretary. It is anticipated that the draft NAIP, as revised with consideration given to public comment and stakeholder input, will be presented to the Secretary in the first quarter of 2015.

DATES: Comments for consideration by NVPO should be received no later than 5:00 p.m. EDT on March 9, 2015.

ADDRESSES: (1) The draft NAIP is available on the web at <http://www.hhs.gov/nvpo/>.

(2) Electronic responses are preferred and may be addressed to: *Rebecca.Fish@hhs.gov*.

(3) Written responses should be addressed to: National Vaccine Program Office, U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 733G, Washington, DC 20201. Attn: HHS Adult Immunization c/o Rebecca Fish.

FOR FURTHER INFORMATION CONTACT: Rebecca Fish, National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone (202) 260-9283; fax (202) 260-1165; email: *Rebecca.Fish@hhs.gov*.

SUPPLEMENTARY INFORMATION: