

The acquisition of Eon by Novartis would increase the concentration in the market significantly.

Entry into manufacture and sale of: (1) Generic desipramine hydrochloride tablets, (2) generic orphenadrine citrate ER tablets, and (3) generic rifampin oral capsules would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Developing and obtaining FDA approval for the manufacture and sale of generic desipramine hydrochloride tablets, generic orphenadrine citrate ER tablets, and generic rifampin oral capsules takes at least two years due to substantial regulatory, technological, and intellectual property barriers.

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for generic desipramine hydrochloride tablets, generic orphenadrine citrate ER tablets, and generic rifampin oral capsules by eliminating actual, direct, and substantial competition between Novartis and Eon; by increasing the likelihood that Novartis will be able to unilaterally exercise market power; by increasing the likelihood and degree of coordinated interaction between the few remaining competitors; and by increasing the likelihood that consumers will pay higher prices.

The proposed Consent Agreement preserves competition in the generic desipramine hydrochloride tablets, generic orphenadrine citrate ER tablets, and generic rifampin oral capsules markets by requiring that Novartis divest all of the Sandoz orphenadrine citrate ER and rifampin assets and all of Eon's desipramine hydrochloride assets to Amide no later than ten days after the acquisition. Amide, a reputable generic manufacturer, is particularly well-positioned to manufacture and market generic rifampin, because Amide already currently contract manufactures generic rifampin capsules for Novartis. Amide is also well-positioned to obtain FDA approval to manufacture and market generic desipramine hydrochloride and orphenadrine citrate ER in the near future. If the Commission determines that Amide is not an acceptable purchaser, or that the manner of the divestiture is not acceptable, Novartis must rescind the transaction with Amide and divest the assets to a Commission-approved buyer not later than six months from the date the Order becomes final. If Novartis fails to divest within the six months, the Commission may appoint a trustee to divest the desipramine hydrochloride,

rifampin, and orphenadrine citrate ER assets.

The proposed remedy contains several provisions designed to ensure the successful divestiture of the desipramine hydrochloride, rifampin, and orphenadrine citrate ER assets to Amide. Novartis must provide various transitional services to enable Amide to compete against Novartis immediately following the divestiture. Novartis is obligated to provide Amide with all inventory of the three divested products and to supply Amide the two products that Amide does not currently manufacture—desipramine hydrochloride and orphenadrine citrate ER—while Amide attempts to obtain FDA approval to manufacture the products for itself in its own facility. Novartis will supply Amide with desipramine hydrochloride for two years, and Amide will have options to extend that supply for two additional one-year periods if Amide is making progress toward approval and needs the additional time to obtain FDA approval. Novartis will supply Amide with orphenadrine citrate ER for four years, and Amide will again have options to extend the supply up to two additional one-year periods as it seeks FDA approval to manufacture orphenadrine citrate for itself. Novartis is also required to provide technology transfer assistance to enable Amide to obtain all necessary FDA approvals to manufacture and sell desipramine hydrochloride, rifampin, and orphenadrine citrate for itself.

The proposed remedy does not provide for a technology transfer or supply obligation for rifampin because Amide is already in possession of the manufacturing technology, having contract manufactured generic rifampin for Novartis for several years.

The proposed remedy also incorporates the use of an Interim Trustee, experienced in obtaining regulatory approval and the manufacture of pharmaceuticals, to oversee the technology transfer and to assist Amide and the Commission in the event of difficulties with supply or delays in obtaining approval. As part of the proposed remedy, Novartis is required to execute an agreement conferring all rights and powers necessary for the Interim Trustee to satisfy his responsibilities under the Order to assure successful divestitures of the desipramine hydrochloride, rifampin, and orphenadrine citrate assets. Novartis has selected Francis J. Civile to be the Interim Monitor and Amide has consented to his selection. The monitor will ensure that the Commission remains informed about

the status of the proposed divestitures and asset transfers.

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 Consent Agreement 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: OS-0990-New]

Agency Information Collection Activities; Proposals Submissions, and Approvals

AGENCY: Office of the Secretary, Office of Assistant Secretary for Planning & Evaluation

Agency Information Collection Activities: Proposed Collection; Comment Request.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection 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.

Type of Information Collection Request: Regular Clearance;

Title of Information Collection: Survey of Frontline Supervisors of Direct Service Workers Participating in the Better Jobs Better Care Demonstration;

Form/OMB No.: OS-0990-New;

Use: The President's New Freedom Initiative specifies goals for enhancing the direct service workforce availability and capability. There is currently a major shortage of direct care workers—

nursing assistants, home health aides, and personal care attendants—who provide care and support to elderly people with chronic diseases and disabilities. Worker shortages are certain to grow as the demand for long-term care increases with the aging population. Thus, recruitment and retention of direct care workers has recently become an issue of interest to policymakers and providers alike. The proposed survey will ensure that HHS and other Federal, state, and local agencies have timely data available on the central role of frontline supervisors in direct care workers job quality and turnover.

Frequency: Reporting, on occasion;

Affected Public: Individuals or households, business or other for profit, not for profit institutions;

Annual Number of Respondents: 906.

Total Annual Responses: 906;

Average Burden Per Response: 30 minutes;

Total Annual Hours: 1,005;

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at <http://www.hhs.gov/oirm/infocollect/pending/> or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to naomi.cook@hhs.gov, or call the Reports Clearance Office on (202) 690-6162.

Written comments and recommendations for the proposed information collections must be received within 60-days, and directed to the OS Paperwork Clearance Officer at the following address: Department of Health and Human Services, Office of the Secretary, Assistant Secretary for Budget, Technology, and Finance, Office of Information and Resource Management, Attention: Naomi Cook (0990-New), Room 531-H, 200 Independence Avenue, SW., Washington DC 20201.

Dated: July 15, 2005.

Robert E. Polson,

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

[FR Doc. 05-14564 Filed 7-22-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Request for Application (RFA) AA068]

Diffusion of Partnership for Health to Health Care and Medical Agencies Serving Persons Living With HIV/AIDS; Notice of Availability of Funds—Amendment

A notice announcing the availability of Fiscal Year (FY) 2005 funds to award a Cooperative Agreement for Diffusion of Partnership for Health to Health Care and Medical Agencies Serving Persons Living with HIV/AIDS was published in the **Federal Register**, on July 14, 2005, Volume 70, Number 134, pages 40704-40708.

The notice is amended as follows:

On page 40704, First column, please change the LOI deadline date to: July 27, 2005. Please change the application deadline date to: August 11, 2005.

On page 40706, Third column, please change the LOI deadline date to: July 27, 2005. Please change the application deadline date to: August 11, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05-14572 Filed 7-22-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Rapid Expansion of Access to HIV/AIDS Prevention, Care and Treatment Interventions Among Rural and Other Underserved Populations in the Republic of Côte d'Ivoire

Announcement Type: New.

Funding Opportunity Number: CDC-RFA-AA057.

Catalog of Federal Domestic Assistance Number: 93.067.

Key Dates:

Application Deadline: August 18, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 301(a) and 307 of the Public Health Service Act [42 U.S.C. Sections 241 and 242], as amended, and under Public Law 108-25 (United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [U.S.C. 7601].

Background: President Bush's Emergency Plan for AIDS Relief has

called for immediate, comprehensive and evidence-based action to turn the tide of global HIV/AIDS. The initiative aims to treat more than two million HIV-infected people with effective combination anti-retroviral therapy by 2008; care for ten million HIV-infected and affected persons, including those orphaned by HIV/AIDS, by 2008; and prevent seven million infections by 2010, with a focus on 15 priority countries, including 12 in sub-Saharan Africa. The five-year strategy for the Emergency Plan is available at the following Internet address: <http://www.state.gov/s/gac/rl/or/c11652.htm>.

Over the same time period, as part of a collective national response, the Emergency Plan goals specific to Côte d'Ivoire are to treat at least 77,000 HIV-infected individuals; care for 385,000 HIV-affected individuals, including orphans; and prevent 265,000 new HIV infections.

Purpose: The purpose of this funding announcement is to progressively build an indigenous, sustainable response to the national HIV epidemic through the rapid expansion of innovative, culturally appropriate, high-quality HIV/AIDS prevention and care interventions, and improved linkages to HIV counseling and testing and HIV treatment services targeting rural and other underserved populations in Côte d'Ivoire.

Under the leadership of the U.S. Global AIDS Coordinator, as part of the President's Emergency Plan, the U.S. Department of Health and Human Services (HHS) works with host countries and other key partners to assess the needs of each country and design a customized program of assistance that fits within the host nation's strategic plan.

HHS focuses on two or three major program areas in each country. Goals and priorities include the following:

- Achieving primary prevention of HIV infection through activities such as expanding confidential counseling and testing programs, building programs to reduce mother-to-child transmission, and strengthening programs to reduce transmission via blood transfusion and medical injections.

- Improving the care and treatment of HIV/AIDS, sexually transmitted diseases (STDs) and related opportunistic infections by improving STD management; enhancing care and treatment of opportunistic infections, including tuberculosis (TB); and initiating programs to provide anti-retroviral therapy (ART).

- Strengthening the capacity of countries to collect and use surveillance data and manage national HIV/AIDS