

further foreclose rivals, in whole or in part, from as much as 40 percent or more of these downstream distribution channels. Transitions' exclusionary conduct has thus likely caused higher prices, lower output, and reduced innovation and consumer choice.

A monopolist may rebut a such a showing of competitive harm by demonstrating that the challenged conduct is reasonably necessary to achieve a procompetitive benefit.<sup>4</sup> Any proffered justification, if proven, must be balanced against the harm caused by the challenged conduct.<sup>5</sup>

No procompetitive efficiencies justify Transitions' exclusionary and anticompetitive conduct. Transitions cannot show that the exclusive arrangements were reasonably necessary to achieve a procompetitive benefit, such as protecting Transitions' intellectual property or technical know-how, or preventing interbrand free-riding.<sup>6</sup> Transitions does not transfer substantial intellectual property or technical know-how to its customers, and even if it did, any such transfer would likely be protected by existing confidentiality agreements.

A concern about interbrand free-riding also does not justify the substantial anticompetitive effects found here. The vast majority of Transitions' promotional efforts are brand specific, reducing the significance of any free-riding concern.<sup>7</sup> While Transitions' marketing efforts may generate some consumer interest in the product category as a whole – and not just in Transitions' own products – this is a part of the natural competitive process. This type of consumer response does not raise a free-riding concern sufficient to justify the substantial anticompetitive effects found here.<sup>8</sup>

### III. The Order

The proposed Order remedies Transitions' anticompetitive and

<sup>4</sup> E.g., *Microsoft*, 253 F.3d at 59.

<sup>5</sup> *Id.*

<sup>6</sup> "Interbrand free-riding" occurs when a manufacturer provides services, training, or other incentives in the promotion of its products for which it cannot easily charge its dealer, and that dealer "free-rides" on these demand-generating services by substituting a cheaper, more profitable product made by another manufacturer that does not invest in comparable services. See generally Howard P. Marvel, *Exclusive Dealing*, 25 J.L. & Econ. 1, 8 (1982).

<sup>7</sup> See *United States v. Dentsply Int'l, Inc.*, 277 F. Supp. 2d 387, 445 (D. Del. 2003), aff'd in rel. part, 399 F.3d at 196-97; Marvel, *Exclusive Dealing*, 25 J.L. & Econ. at 8 (explaining that an interbrand free-riding justification "does not apply if the promotional investment is purely brand specific. In such cases, the dealer will not be in a position to switch customers from brand to brand.").

<sup>8</sup> See *In re Polygram*, 136 F.T.C. 310, 361-62 (2003), aff'd, 416 F.3d 29, 37-38 (D.C. Cir. 2005).

exclusionary conduct and imposes certain fencing-in requirements that are designed to prevent *de facto* exclusive dealing.<sup>9</sup> Paragraph II of the Order addresses the core of Transitions' exclusionary conduct and seeks to lower entry barriers and to restore competition. Paragraph III requires Transitions to implement an antitrust compliance program, which includes providing notice of this Order to Transitions' customers. Paragraphs IV-VI impose reporting and other compliance requirements. The Order expires in 20 years unless otherwise indicated.

Paragraph II.A prohibits Transitions from adopting or implementing any agreement or policy that results in "exclusivity" with lens casters, or its "Direct Customers." "Exclusivity" is defined in the Order to include any requirement that a customer limit or refrain from dealing with a competing photochromic lens, as well as any requirement that a customer give Transitions' products more favorable treatment as compared to a competitor's products.

Paragraph II.B allows Transitions to enter into exclusive agreements with retailers and wholesale labs ("Indirect Customers"), provided certain safeguards are met. Specifically, any exclusive agreements with Indirect Customers must: i) be terminable without cause, and without penalty, on 30 days written notice; ii) be available on a partially exclusive basis, if requested by the customer; and iii) not offer flat payments of monies in exchange for exclusivity. These provisions, along with Paragraph II.E, which prohibits Transitions from bundling discounts, are designed to enable a competitor or entrant to compete for a customer's business, even if it does not offer a photochromic treatment that applies to a full line of ophthalmic lenses. Creating conditions conducive to effective entry on an incremental basis is likely to hasten new entry and to restore competition.

Under Paragraph II.C, Transitions may not limit its customers from communicating or discussing a competing photochromic lens with consumers and others. This Paragraph also requires Transitions to allow a lens caster or another customer that sells Transitions' photochromic treatment on a particular brand of lens to sell a competitors' photochromic treatment on the same brand.

<sup>9</sup> We use the term "*de facto* exclusive dealing" to refer to practices that significantly deter a customer from purchasing or selling a competing photochromic lens.

Paragraph II.D has two provisions designed to prevent *de facto* exclusive dealing through pricing policies. First, Transitions cannot offer market share discounts, *i.e.*, discounts based on the percentage of a customer's sales of Transitions' lenses as a percentage of all photochromic lens sales. Second, Transitions cannot offer discounts that are applied retroactively once a customer reaches a specified threshold. For example, Transitions may provide a discount on sales beyond 1000 units but it may not lower the price of the first 999 units if and when the customer buys the 1000<sup>th</sup> unit. The provisions in Paragraph II.D, along with Paragraph II.E, will be in effect for 10 years.

Notwithstanding any provision of the Order, Paragraph II.G explicitly allows Transitions to provide volume discounts that reflect certain cost differences, and to offer discounts to meet competition. It also allows Transitions to require that any monies it provides to customers be used solely for the manufacture, promotion or sale of Transitions lenses.

Finally, Paragraph II.F prohibits Transitions from retaliating against a customer that purchases or sells Transitions lenses on a non-exclusive basis.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 2010-4979 Filed 3-8-10; 7:23 am]

BILLING CODE 6750-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-10-09AM]

### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

### Proposed Project

Prevalence Survey of Healthcare Associated Infections (HAIs) and

Antimicrobial Use in U.S. Acute Care Hospitals—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (proposed), Centers for Disease Control and Prevention (CDC).

#### *Background and Brief Description*

CDC is requesting OMB approval to conduct two surveys to obtain national estimates of HAI prevalence and antimicrobial use in the United States. Preventing HAIs is a CDC priority, and an essential step in reducing the occurrence of HAIs is to accurately estimate the burden of these infections in U.S. hospitals and to describe the types of HAIs and their causative organisms, including antimicrobial-resistant pathogens.

The scope and magnitude of HAIs in the U.S. were last directly estimated in the 1970s and 1980s by CDC's Study on the Efficacy of Nosocomial Infection Control (SENIC), in which comprehensive data were collected from a sample of 338 hospitals; 5% of hospitalized patients acquired an infection not present at the time of admission. CDC's current HAI surveillance system, the National Healthcare Safety Network (NHSN) (OMB Control No. 0920–0666, expiration date 9/30/2012), focuses instead on device-associated and procedure-associated infections in a variety of patient locations, and does not receive data on all types of HAIs to make hospital-wide burden estimates. The purpose of this information collection request is to assess the magnitude and types of HAIs and antimicrobial use occurring in all patient populations within acute care hospitals. This information will be used to inform decisions made by local and national policy makers and hospital infection control personnel regarding appropriate targets and strategies for

preventing HAIs and the emergence of antimicrobial-resistant pathogens and encouraging appropriate antimicrobial use. Such assessments can be obtained in periodic national prevalence studies, such as those that have been conducted in several European countries.

CDC proposes to conduct two surveys to collect this data. The first survey will be a limited roll-out survey and will be conducted in 30 facilities across 10 states in collaboration with state public health authorities and CDC's Emerging Infections Program (EIP). The survey will be conducted on a single day in participating facilities. Infection Control Practitioners in participating facilities, such as infection control personnel, will collect limited demographic and clinical information on a sample of eligible inpatients and, on the same day, EIP site personnel will collect information on HAIs and antimicrobial use for surveyed patients who are on antimicrobial therapy at the time of the survey. The second survey will involve 500 facilities across the same 10 states and use the same methodology. As with the first survey, CDC will collaborate with state public health authorities and EIP sites.

CDC has made the following assumptions in calculating the response burden. Infection Control Practitioners will be asked to collect a minimal amount of data, limited to basic demographic and risk factor/antimicrobial use information. We anticipate that this data collection will take 5 minutes per patient. EIP personnel will complete data collection on antimicrobial use and HAIs. CDC estimates that this data collection will take approximately 15 minutes per patient.

CDC has assumed an average daily patient census of 250 patients for each of the 30 participating facilities in Survey #1. An Infection Control

Practitioner (ICP) in his/her own facility will be asked to review  $\frac{1}{3}$  or 33% of this number (250); thus, the ICP would review 82.5 records (rounded up to 83). This number is estimated to be the same in each phase of the prevalence survey effort.

EIP Personnel will be reviewing medical records of approximately 40% of all patients surveyed in their EIP site in both surveys #1 and #2. In Survey #1, the total number of patient records surveyed in each EIP site (assuming 3 facilities in each EIP site and 83 patient records per site) is 247.5 patient records. Forty percent of that number (247.5) is 99 patient records or 99 responses per EIP site. In Survey #2, there will be more facilities participating per EIP site (50 facilities per EIP site for a total of 500 facilities). Again, CDC assumes 82.5 records surveyed per site ( $50 \times 82.5$ ) or a total of 4,125 patient records. As above, EIP personnel in each of the 10 sites will review approximately 40% of the 4,125 patient records per site or 1,650 patient records.

CDC will use the data provided to estimate the prevalence of HAIs and antimicrobial use across this sample of U.S. hospitals as well as to estimate the distribution of infection types, causative organisms, and nature of and rationale for antimicrobial use.

This proposed project supports CDC's Strategic Goal of "Healthy Healthcare Settings," specifically the objectives to "Promote compliance with evidence-based guidelines for preventing, identifying, and managing disease in healthcare settings" and "Prevent adverse events in patients and healthcare workers in healthcare settings."

There are no costs to respondents, other than their time to complete the survey. The total annualized burden for this data collection is 8,039 hours.

#### ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Infection Control Practitioners—Survey #1 .....	30	83	5/60
EIP Personnel—Survey #1 .....	10	99	15/60
Infection Control Practitioners—Survey #2 .....	500	83	5/60
EIP Personnel—Survey #2 .....	10	1,650	15/60

Dated: February 26, 2010.

**Maryam I. Daneshvar,**  
*Acting Reports Clearance Officer, Centers for  
 Disease Control and Prevention.*  
 [FR Doc. 2010-4885 Filed 3-8-10; 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:* Child Support Enforcement Program Expenditure Report (Form OCSE-396A) and the Child Support Enforcement Program Collection Report (Form OCSE-34A).

*OMB No.:* 0970-0181.

*Description:* State and Tribal agencies administering the Child Support Enforcement Program under Title IV-D of the Social Security Act are required to provide information each fiscal

quarter to the Office of Child Support Enforcement (OCSE) concerning administrative expenditures and the receipt and disposition of child support payments from non-custodial parents. State title IV-D agencies report quarterly expenditures and collections using Forms OCSE-396A and OCSE-34A, respectively. Tribal title IV-D agencies report quarterly expenditures using Form SF-269, as prescribed in program regulations, and formerly reported quarterly collections using only a modified version of Form OCSE-34A. The information collected on these reporting forms is used to compute quarterly grant awards to States and Tribes, the annual incentive payments to States and provides valuable information on program finances. This information is also included in a published annual statistical and financial report, available to the general public.

Under Public Law 111-5, the "American Recovery and Reinvestment Act of 2009" (ARRA), enacted in February 2009, the availability of

Federal funding to State administered child support enforcement programs was substantially increased with a change in methodology of calculating these funds. We propose to formally incorporate this necessary revision into the quarterly expenditure report and to update the existing quarterly collection report to enable the same version of that form to be used by both State and Tribal IV-D agencies. We also propose to review other data entry elements and the accompanying instructions in both data collection forms to assure that the financial information requested from States and Tribes remains relevant and will assure that OCSE collects the information needed in the most efficient format feasible.

*Respondents:* State agencies (including the District of Columbia, Puerto Rico, Guam and the Virgin Islands) administering the Child Support Enforcement Program. Tribal agencies with approved plans to administer the Child Support Enforcement Program.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-396A .....	54	4	8	1,728
OCSE-34A .....	100	4	8	3,200

Estimated Total Annual Burden Hours: 4,928.

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. *E-mail address:* [infocollect@acf.hhs.gov](mailto:infocollect@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.

Dated: March 3, 2010.

**Robert Sargs,**  
*Reports Clearance Officer.*  
 [FR Doc. 2010-4895 Filed 3-8-10; 8:45 am]  
**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2008-P-0435 and FDA-2008-P-0554]

#### Determination That DOVONEX (Calcipotriene) Ointment, 0.005%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its determination that DOVONEX (calcipotriene) Ointment, 0.005%, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for calcipotriene Ointment, 0.005%, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire