

Further, the Colegio is prohibited from communicating to any payer or provider any term, condition, or requirement on which Colegio members are willing or unwilling to deal with a payer or provider, and from communicating with any member concerning the desirability or appropriateness of any term or condition of a payer relating to dental services, or whether the plan is open to participation by all Colegio members. The Colegio cannot facilitate in any manner, or transfer the exchange of, information concerning dentists' intentions to contract with any payer, or under what terms.

The proposed order does not restrict legitimate communications between the Colegio and payers. Health care practitioners' provision of certain kinds of information to payers is not likely to raise antitrust concerns, but instead may serve to promote competition and benefit consumers. For example, the DOJ/FTC Statements of Enforcement Policy in Health Care (1996) define two "antitrust safety zones" dealing with the provision of information to payers, and state that conduct falling within these safety zones will not be challenged by the enforcement agencies absent extraordinary circumstances.¹ The proposed order does not prohibit the Colegio from engaging in activities encompassed in these safety zones, or from communicating with payers about other matters, unless the communication is part of an agreement or course of conduct specifically prohibited by the order.

The proposed order likewise does not restrict the right of the Colegio to provide government bodies with information and opinions in an effort to influence legislation or regulatory action. A proviso states explicitly that the order does not prohibit the Colegio from petitioning any federal, state, or Commonwealth government executive agency or legislative body concerning legislation, rules, or procedures, or from

participating in any federal, state, or Commonwealth administrative or judicial proceeding, insofar as the activity is protected from antitrust scrutiny by the *Noerr-Pennington* doctrine.² That doctrine does not, however, protect price-fixing agreements, refusals to deal, or similar conduct designed to obtain higher prices from government purchasers.³

Part III of the proposed order prohibits the Colegio from restricting truthful advertising of dental services or solicitation of patients. The Colegio, however, can formulate, adopt, disseminate, and enforce reasonable ethical guidelines governing the conduct of its members with respect to representations that respondent reasonably believes would be false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act, or with respect to uninvited in-person solicitation of actual or potential patients who, because of their particular circumstances, are vulnerable to undue influence.

Part IV of the proposed order requires the Colegio to distribute copies of the order and accompanying complaint to its employees and members, and to payers or providers who since January 1, 1995, communicated a desire or interest in contracting for dentists' services. Part IV also requires the Colegio to maintain certain records pertaining to advertising for a period of ten years, while other order provisions will remain in effect for twenty years. Parts V and VI of the proposed order impose certain reporting requirements, while Part VII of the proposed order provides for access to the Colegio's documents and personnel. Parts V, VI, and VII are to assist the Commission in monitoring compliance with the proposed order.

Opportunity for Public Comment

The proposed order has been placed on the public record for sixty (60) days in order to receive public comments from interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The purpose of this analysis is to facilitate public comment on the agreement. The analysis is not intended to constitute an official interpretation of the agreement, the proposed complaint, or the proposed consent order, or to modify their 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

Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

Project 1. First Follow-Up Survey of Youth and Site Visit and Focus Group Protocols for the Federal Evaluation of Initiatives Funded Under Section 510 of the Maternal and Child Health Block Grant Program—The Personal Responsibility and Work Opportunity Reconciliation Act (Public Law 104-193) established Section 510 of the Maternal and Child Health Block Grant Program, the purpose of which is to support state efforts promoting abstinence only education. The Balanced Budget Act of 1997 (Pub. L. 105-33) established a requirement to "evaluate programs under Section 510." This proposed information collection will gather follow-up information for the evaluation—NEW—Respondents: Individuals, state or local governments—Burden Information for First Follow-Up Survey—Number of Respondents: 6,510; Average Burden per Response: .75 hours; Burden: 4,883 hours—Burden Information for Focus Groups—Number of Respondents: 380; Average Burden per Response: 2 hours; Burden: 760 hours—Burden Information for Executive Interviews—Number of Respondents: 330; Average Burden per Response: 1.5 hours; Burden: 495 hours—Total Burden: 6,138 hours.

OMB Desk Officer: Allison Eydt.

Copies of the information collection packages listed above can be obtained

¹ Statement 5 provides a safety zone for providers' collective provision of "factual information concerning the providers' current or historical fees or other aspects of reimbursement, such as discounts or alternative reimbursement methods accepted * * *," so long as collection of the information meets certain requirements designed to ensure that the exchange of price or cost data is not used by competing providers to discuss or coordinate costs or prices. Statements at 44-45. The safety zone in Statement 4 covers the provision of "underlying medical data that may improve purchasers' resolution of issues relating to the mode, quality, or efficiency of treatment," as well as providers' "development of suggested practice parameters—standards for patient management developed to assist providers in clinical decisionmaking—that also may provide useful information to patients, providers, and purchasers." Statements at 41.

² See, e.g., *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411 (1990); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961).

³ *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. at 424-425.

by calling the OS Reports Clearance Officer on (202) 690-6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW, Washington DC, 20201. Written comments should be received within 30 days of this notice.

Dated: March 24, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

1. Site Visit Protocols for the Multi-Site Evaluation of the Welfare-to-Work Grant Program—0990-0230—Revision—This data collection will provide site specific information for a sample of Welfare-to-Work (WtW) grant programs which will support the Office of the Assistant Secretary for Planning and Evaluation in its efforts to further document the status of the grants program and provide information on implementation issues as part of the Congressionally mandated evaluation of the WtW grants program. Respondents: Individuals, State, Local or Tribal Governments, Non-profit Institutions—Burden Information for Staff Interviews—Number of Responses: 360; Burden per Response: 1 hour; Total Burden for Staff Interviews: 360 hours—Burden Information for Focus Groups—Number of Responses: 350; Burden per Response: 1.5 hours; Total Burden for Focus Groups: 540 hours—Burden Information for Individual Tribal

Program Participants—Number of Responses: 50; Burden per Response: .5 hours; Total Burden for Tribal Participants: 30 hours—Total Burden—930 hours.

2. Follow-up Survey for the Multi-Site Evaluation of the Welfare-to-Work Grant Program—New—This information collection will support the Office of the Assistant Secretary for Planning and Evaluation in its efforts to evaluate the WtW grant program by obtaining detailed information on program participants circumstances and experiences with the program. Respondents: Individuals; Number of Responses: 7225; Number of Responses: 12,750; Burden per Response: 46 minutes; Total Burden: 9819 hours; OMB Desk Officer: Allison Eyd.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690-6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW, Washington, DC, 20201. Written comments should be received within 30 days of this notice.

Dated: March 24, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N-0304]

Dietary Supplements Containing Ephedrine Alkaloids; Administrative Docket Update; Availability

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of certain documents to update the administrative docket of the proposed rule on dietary supplements containing ephedrine alkaloids. This action is being taken to ensure that interested persons are aware of the

updated information. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing certain provisions of the proposed rule on dietary supplements containing ephedrine alkaloids, and establishing a new docket that will contain new adverse event reports and related information concerning these products.

FOR FURTHER INFORMATION CONTACT:

Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HFS-7), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301-827-6733.

SUPPLEMENTARY INFORMATION:

I. Background (Proposed Rule)

In the **Federal Register** of June 4, 1997 (62 FR 30678), FDA published a proposed rule on dietary supplements containing ephedrine alkaloids (the "ephedrine alkaloids proposal"). That proposal would have established a finding that a dietary supplement is adulterated if it contains 8 milligrams or more of ephedrine alkaloids per single serving, required that the labels of products that contain ephedrine alkaloids state, "Don't use this product for more than 7 days," required certain warning statements, and affected other aspects of product labeling for such products. FDA proposed this action after receiving over 800 adverse events associated with the use of dietary supplements that contained, or were suspected to contain, ephedrine alkaloids, and reviewing scientific literature and other data concerning ephedrine alkaloids. FDA received approximately 14,775 comments in response to the ephedrine alkaloids proposal.

II. Updated Information

FDA is updating the docket for the ephedrine alkaloids proposal with additional information, most of which was received after publication of the proposal.

FDA received 270 additional adverse event reports between February and September 1997. FDA added these adverse event reports to the ephedrine alkaloids proposal's docket in two submissions without formal clinical analysis. FDA did not rely on these 270 reports in the ephedrine alkaloids proposal because FDA received them after it began its analysis for the proposal.

FDA has received additional documentation (e.g., copies of product labels and labeling, information on how the consumers used the products at issue and available medical or other clinical records) concerning