Board of Governors of the Federal Reserve System, October 9, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–27341 Filed 10–15–97; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 962–3072]

Ashland, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 15, 1997.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Elaine D. Kolish, Federal Trade Commission, S–4302, 6th St. and Pennsylvania Ave., NW., Washington, DC 20580. (202) 326–3042. Robert Frisby, Federal Trade Commission, S–4302, 6th St. and Pennsylvania Ave., NW., Washington, DC 20580. (202) 326–2098.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, and section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the accompanying complaint. An electronic copy of the full text of the consent agreement package can be obtained from the Commission Actions section of the FTC Home Page (for October 8, 1997), on the World Wide Web, at ''http://www.ftc.gov/os/actions97.htm.'' A paper copy can be obtained from the FTC Public Reference Room, Room H–130, Sixth Street and Pennsylvania Ave., NW., Washington, DC 20580 either in person or by calling (202) 326–3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement to a proposed consent order from Ashland, Inc. (''Ashland''). The agreement would settle a proposed complaint by the Federal Trade Commission that Ashland engaged in unfair or deceptive acts or practices in violation of section 5(a) of the Federal Trade Commission Act.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by 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.

This matter concerns advertising practices related to the sale of Valvoline TM8 Engine Treatment (''TM8''). The proposed complaint charges that, through the use of statements contained in its advertisements and promotional materials, Ashland made the following unsubstantiated representations: (1) TM8 bonds Teflon to engine parts; (2) compared to motor oil alone, TM8: reduces engine wear; reduces camshaft bearing wear by up to 75%; reduces main bearing wear by up to 75%; under high temperature conditions experienced by engines, provides twice as much wear protection; extends the duration of engine life; and improves fuel economy; and (3) One treatment of TM8 lasts for 50,000 miles. Lastly, the proposed complaint alleges that Ashland falsely represented that tests prove that, compared to motor oil alone, TM8: reduces camshaft bearing wear by up to 75%; reduces main bearing wear by up to 75%; under high temperature conditions experienced by engines, provides twice as much wear protection; and improves fuel economy.

The proposed consent order contains provisions designed to prevent Ashland from engaging in similar acts and practices in the future. Part I of the proposed order prohibits Ashland from making any representation about the performance or attributes of any engine treatment unless, at the time it makes the representation, Ashland possesses and relies upon competent and reliable evidence, which when appropriate must be scientific evidence, that substantiates the representation. Part I also prohibits Ashland from misrepresenting the results of tests or studies.

The proposed order also contains standards provisions regarding record-keeping, notification of changes in corporate status, distribution of the order, termination of the order, and the filing of a compliance report.

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

Donald S. Clark,

Secretary.

[FR Doc. 97–27358 Filed 10–15–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices; Product Development Protocol; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), in cooperation with the Health Industry Manufacturers Association (HIMA), is announcing a public workshop to discuss use of the Product Development Protocol (PDP) as an alternate means for medical device approval. This public workshop is being held so that FDA may gather information to assist in developing an efficient, practical PDP process.

DATES: The public workshop will be held on Wednesday, October 22, 1997, 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Renaissance Hotel, 999 9th St. NW., Washington, DC 20001. Attendees requiring overnight accommodations may contact the hotel at 202–898–9000 and reference the FDA/HIMA meeting to ensure conference rates. To register for the public workshop, contact HIMA, Meetings Department, 1200 G St. NW., Washington, DC 20005, 202–434–7237.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Center for Devices and Radiological Health (HFZ–470), 9200

Corporate Blvd., Rockville, MD 20850, 301– 594–5072, FAX 301–480–4224.

SUPPLEMENTARY INFORMATION: FDA, in cooperation with HIMA, is holding a public workshop to discuss the implementation of a different process for the premarket approval of class III devices by means of a PDP. Section 515(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e (f)) (the act) provides for a product development protocol as an alternate means of premarket approval of class III medical devices. Although the PDP has existed as a means of approval of a medical device since the Medical Device Amendments of 1976 (Pub. L. 94–295) to the act, the PDP has never been completely implemented. As part of it's reengineering initiative, the Center for Devices and Radiological Health (CDRH) of FDA established the PDP Reengineering Team, comprised of FDA staff, in consultation with industry representatives, to develop an efficient, practical PDP process.

The intent of the PDP process is to substitute the conventional device approval model, the sequential process of clinical investigation followed by a premarket approval application, with an early interaction between the sponsor and FDA to produce a focused product development plan that merges the two steps. A PDP team has developed guidelines for creating this focused development protocol that will be described at the public workshop. Workshop participants will have ample opportunity to ask questions as the new PDP process is described and case studies on particular examples of class III devices are presented. Background information, a detailed flow chart, and a descriptive narrative regarding the proposed PDP process can be found at the FDA/CDRH Web site at the address below.

Additional information is available on the FDA Web page (www.fda.gov/cdrh/pdp/pdp.html) or the HIMA Web page (www.himanet.com).

Dated: September 30, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–27433 Filed 10–15–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited 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) ways to enhance 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.

Proposed Projects

1. Project To Assess Bi/Multilingual Services Offered at Selected Community and Migrant Health Centers—NEW

Recognizing the importance of language-appropriate services to full and effective health care provision, the Office of Minority and Women's Health in the Bureau of Primary Health Care [BPHC], Health Resources and Services Administration [HRSA], proposes to conduct a voluntary telephone survey to assess the composition and provision of bi/multilingual services at a sample of 40 Community and Migrant Health Centers [C/MHCs] selected from those C/MHCs indentified as likely to be serving high percentages of people who speak languages other than English. This effort was developed so that information could be gathered to assist the field, funding agency staff, and policymakers in better understanding what methods are being used to provide services to these populations, what works, what does not, and barriers and facilitators to effective health service provision for speakers of languages other than English.

The information gathered will provide HRSA with an information base upon which to build in making future program decisions regarding C/MHC resource and staffing needs in order to reduce or eliminate the barriers to health care often faced by non-or limited-English-speaking populations. The end result of the program will be to assist the funding agency to help C/MHCs and by extension, other providers of health care for non-or limited-English speaking populations to provide appropriate services. An estimate of the hour burden for the 40 C/MHC Directors selected for the survey is shown below.

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Bi/Multilingual Services Survey	40 C/MHC Directors	1	2	80

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 9, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97–27429 Filed 10–15–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is