discussed above, private-sector ACH operators manage their settlement risk by limiting their services to those institutions that meet their admission criteria. Nevertheless, private-sector ACH operators could require prefunding from their participants as an additional risk control measure, if they chose to do so. Thus, the Board does not believe that settlement-day finality for ACH credit transactions processed by the Federal Reserve and conditioned on the expanded use of prefunding would adversely affect competition in the provision of interbank ACH services.

By order of the Board of Governors of the Federal Reserve System, November 10, 1999.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 99–29991 Filed 11–16–99; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 991 0240]

Precision Castparts Corp., et al.; 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 10, 1999.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Richard Parker or Matthew Reilly, FTC/H–374, 600 Pennsylvania Ave., NW, Washington, DC 20580. (202) 326–2574 or 326–2350.

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 thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 10, 1999), 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, 600 Pennsylvania Avenue, NW, Washington, DC 20580, either in person or by calling (202) 326–3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW, Washington, DC 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. 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 (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') and Decision & Order from Precision Castparts Corp. (''PCC'') and Wyman-Gordon Company (''Wyman-Gordon'') designed to remedy the anticompetitive effects resulting from PCC's acquisition of all of the voting securities of Wyman-Gordon. Under the terms of the Consent Agreement, PCC and Wyman-Gordon will be required to divest the following assets that are involved in the development, manufacture and sale of titanium, stainless steel and nickel-based superalloy aerospace investment cast components: (1) Wyman-Gordon's titanium foundry located in Albany, Oregon; and (2) Wyman-Gordon's Large Cast Parts foundry located in Groton, Connecticut.

The proposed Consent Agreement and Decision & Order have been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Order and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement or make final the proposed Decision & Order.

Pursuant to a May 17, 1999 cash tender offer, PCC agreed to acquire 100% of the voting securities of Wyman-Gordon for approximately $721 million. The proposed Complaint alleges that this agreement violates section 5 of the FTC Act, as amended, 15 U.S.C. 18, and the acquisition of Wyman-Gordon by PCC, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 45, and Section 5 of the FTC Act, as amended, 15 U.S.C. 18, in the markets for titanium, large stainless steel, and large nickel-based superalloy aerospace investment cast structural components.

Investment casting is a method of manufacturing metal components whereby a wax model of the metal component is dipped into a ceramic slurry which dries to form a ceramic shell. The wax is then melted out using a special furnace, leaving a cavity within the ceramic shell into which molten metal is poured. Once the metal cools, the ceramic shell removed, producing dimensionally precise metal components. Aerospace investment cast structural components are components that are used primarily in aerospace jet engine and aerospace airframe applications and are manufactured using a variety of metal alloys, including titanium, stainless steel, and nickel-based superalloy. PCC and Wyman-Gordon are two of the world's leading suppliers of titanium, stainless steel, and nickel-based superalloy aerospace investment cast structural components. While each of these metals, and others including aluminum, can be used in many aerospace applications, for a particular application, one metal is typically far superior to the alternatives based on cost, weight, and strength considerations. Therefore, based on design specifications and performance characteristics, a component produced from a particular metal is not a reasonable competitive alternative for an investment cast aerospace structural component manufactured using a different metal.

Metal aerospace structural components can also be produced utilizing other methods of manufacturing, such as forging and fabrication. While these other methods of manufacturing are alternatives to investment casting, the investment casting process provides the most cost-effective method of producing the required components for those aerospace applications where investment castings are currently used. In view of this cost distinction, other methods of manufacturing are not

reasonable competitive alternatives for the production of titanium, stainless steel, and nickel-based superalloy aerospace investment cast structural components.

Titanium, large stainless steel, and large nickel-based superalloy investment cast structural aerospace components are each relevant markets. The worldwide market for titanium aerospace investment cast structural components is highly concentrated, and the proposed acquisition would substantially increase concentration in the market. PCC and Wyman-Gordon are two of only four viable suppliers of titanium aerospace investment cast structural components, and one of the remaining two competitors is significantly smaller than the other three.

The worldwide market for large (greater than 24 inches in diameter) stainless steel aerospace investment cast structural components is also highly concentrated, and the acquisition would substantially increase concentration in this market. PCC and Wyman-Gordon are two of only six viable suppliers of large stainless steel aerospace investment cast structural components.

The worldwide market for large (greater than 24 inches in diameter) nickel-based superalloy aerospace investment cast structural components is also highly concentrated, and the acquisition would substantially increase concentration in this market. PCC and Wyman-Gordon are two of only four viable suppliers of large nickel-based superalloy aerospace investment cast structural components.

By eliminating competition between PCC and Wyman-Gordon in these highly concentrated markets, the proposed acquisition would have allowed PCC to unilaterally exercise market power, and would have enhanced the likelihood of coordinated interaction among the remaining firms in these markets, thereby increasing the likelihood that: (1) consumers of titanium, large stainless steel, and large nickel-based superalloy aerospace investment cast components would be forced to pay higher prices; and (2) innovation in these markets would decrease.

It is unlikely that the competition eliminated by the proposed acquisition would have been replaced by new entrants into the relevant markets within two years due to the substantial barriers to entry into the markets at issue. A new entrant into these markets would need to undertake the difficult, expensive, and time-consuming process of developing a new product. Moreover, a new entrant would likely have to purchase a new facility, as well as specialized investment casting equipment. A new entrant would also have to undertake the arduous task of developing the required engineering and process expertise. In addition, because of the critical nature of aerospace investment cast structural components, a new entrant would have to obtain customer and other third-party certifications and approvals before it could begin to manufacture and sell aerospace investment cast components. Finally, customers of aerospace investment cast structural components are generally reluctant to contract with suppliers that have not developed a proven reputation for quality and reliability. For these reasons, new entry into the market would in all likelihood not occur in time to deter or counteract the anticompetitive effects resulting from the acquisition.

The proposed Consent Agreement and Decision & Order effectively remedy the acquisition's anticompetitive effects in the market for titanium aerospace investment cast structural components by requiring PCC and Wyman-Gordon to divest Wyman-Gordon's titanium foundry in Albany, Oregon to a Commission-approved acquirer. Pursuant to the Consent Agreement and Decision & Order, PCC and Wyman-Gordon are required to divest the Albany titanium foundry no later than six (6) months from the date the Commission accepts the Consent Agreement and Decision & Order for public comment. In the event that PCC and Wyman-Gordon fail to divest the assets within the required time, the Commission may appoint a trustee to divest the assets. Wyman-Gordon only recently acquired control of the Albany titanium foundry and had not yet integrated the foundry into its castings operation and business. As a result, the Commission did not require that PCC and Wyman-Gordon divest Wyman-Gordon's Albany titanium foundry to a purchaser identified and approved by the Commission prior to the consummation of the Wyman-Gordon acquisition.

The proposed Consent Agreement and Decision & Order effectively remedy the acquisition's anticompetitive effects in the markets for large stainless steel and large nickel-based superalloy aerospace investment cast structural components by requiring PCC and Wyman-Gordon to divest the Wyman-Gordon's Large Cast parts (''LCP'') foundry in Groton, Connecticut to Doncasters plc, a leading international manufacturer of aerospace investment cast components. Pursuant to the Consent Agreement and Decision & Order, PCC and Wyman-Gordon are required to divest the Groton LCP foundry to Doncasters no later than 16 business days from the date the Commission accepts the Consent Agreement and Decision & Order for public comment. In the event PCC and Wyman-Gordon fail to divest the Groton LCP foundry to Doncasters within the required time, the Consent Agreement contains a ''crown jewel'' provision that allows the Commission to appoint a trustee to divest both Wyman-Gordon's LCP and Small Cast parts (''SCP'') foundries located in Groton, Connecticut, to an acquirer approved by the Commission.

The proposed Consent Agreement and Decision & Order require PCC and Wyman-Gordon to assist the acquirers of the divested assets so that they can compete effectively in the markets for titanium, large stainless steel, and large nickel-based superalloy aerospace investment cast components. PCC and Wyman-Gordon must provide sufficient technical assistance and advice to the acquirers in order that they may begin manufacturing and selling titanium, stainless steel, and nickel-based superalloy aerospace investment cast components. Further, at the request of a customer of titanium, stainless steel, or nickel-based superalloy aerospace investment cast components at any time during the next year, PCC and Wyman-Gordon must transfer to the Albany titanium facility, the Groton LCP foundry, or both the Groton LCP and SCP foundries, as applicable, all tooling and manufacturing know-how associated with producing a particular component identified by the customer. PCC and Wyman-Gordon must also pay (a) all costs reasonably incurred in the delivery of such tooling and manufacturing know-how; (b) fifty (50) percent of the costs reasonably incurred in conforming such tooling to substantially the same quality employed or achieved by Wyman-Gordon; and (c) fifty (50) percent of the costs related to receiving any certifications or approvals from the customer that may be required as a result of the transfer of the assets.

To ensure that the acquirers of the divested assets have the opportunity to retain all the key employees currently involved in Wyman-Gordon's titanium, large stainless steel and large nickel-based superalloy aerospace casting businesses, the Consent Agreement and Decision & Order require that PCC and Wyman-Gordon provide financial incentives to these individuals, including a bonus for certain employees for accepting employment with the acquirer. Further, the Consent Agreement and Decision & Order require PCC and Wyman-Gordon to provide to the Commission a report of

compliance with the divestiture provisions of the Decision & Order within thirty (30) days following the date the Decision & Order becomes final, and every thirty (30) days until PCC and Wyman-Gordon have completed the divestitures. Finally, an Order to Hold Separate issued by the Commission requires that the Albany titanium foundry, and if necessary the Groton LCP and Groton SCP, be operated independently of PCC and Wyman-Gordon until the divestitures are completed.

The purpose of this analysis is to facilitate public comment on the Consent Agreement and Decision & Order, and it is not intended to constitute an official interpretation of the Consent Agreement and Decision & Order or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 99–29997 Filed 11–16–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99P–4064]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received a petition requesting an exemption from the premarket notification requirements for vascular tunnelers. FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments by December 17, 1999.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (Public Law 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142). In the **Federal Register** of November 3, 1998 (63 FR 59222), FDA published a final rule codifying those exemptions.

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the World Wide Web (WWW) on the CDRH home page at http://www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petitions

On September 14, 1999, FDA received a petition from IMPRA, Inc., requesting an exemption from premarket notification for vascular tunnelers. Vascular tunnelers are currently classified under 21 CFR 870.3460 as an accessory.

IV. Comments

Interested persons may, on or before December 17, 1999, submit to the