FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative. Federal Trade Commission, Premeger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580. (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 02–18703 Filed 7–23–02; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[File No. 021 0059]

Amgen Inc. and Immunex Corporation; 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 August 12, 2002.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: *consentagreement@ftc.gov,* as prescribed below.

FOR FURTHER INFORMATION CONTACT: Elizabeth Jex, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–3273.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), 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 July 12, 2002), on the World Wide Web, at ''*http://www.ftc.gov/os/2002/07/index.htm.*'' A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled ''confidential.'' Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: *consentagreement@ftc.gov.* Such comments 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 Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an agreement containing a proposed Consent Order from Amgen Inc. (''Amgen'') and Immunex Corporation (''Immunex'') that is designed to remedy the anticompetitive effects of the merger of Amgen and Immunex. Under the terms of the agreement, the companies would be required to: (1) Divest of all Immunex's assets relating to Leukine (a neutrophil regeneration factor) to Schering AG (''Schering''); (2) license certain Amgen patents relating to its tumor necrosis factor (''TNF'') receptor to Serono S.A. (''Serono''); and (3) license certain Amgen and Immunex patents relating to the development of Interleukin-1 (''IL–1'') receptors to Regeneron Pharmaceuticals Inc. (''Regeneron'').

The proposed Consent Order has been placed on the public record for thirty (30) days for receipt 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 agreement and any comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed Consent Order.

In their merger agreement of December 16, 2001, Amgen and Immunex propose to combine their two companies in a transaction valued at approximately $16 billion. Thereafter, the merged entity will be called Amgen Inc. The proposed Complaint alleges that the proposed merger, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and section 5 of the FTC Act, as amended, 15 U.S.C. 45, in the markets for: (1) Neutrophil regeneration factors; (2) TNF inhibitors; and (3) IL–1 inhibitors. The proposed Consent Order would remedy the alleged violations by replacing the lost competition in each of these markets that would result from the merger.

Neutrophil Regeneration Factors

Neutrophil regeneration factors are used to treat neutropenia, the suppression of production of certain white blood cells (known as ''neutrophils'') which often results from chemotherapy. Immunex's product, Leukine, stimulates the production of both granulocytes and macrophages, two types of neutrophils, while Amgen's products, Neupogen and Neulasta, stimulate the production of granulocytes. The use of these products to stimulate neutrophil regeneration allows patients to maintain a robust immune system while continuing with their chemotherapy regimens. Annual U.S. sales of neutrophil regeneration factors total approximately $1.2 billion.

The market for neutrophil regeneration factors is highly concentrated. Amgen and Immunex are the only companies with neutrophil regeneration factors approved for sale in the United States. Amgen's Neupogen is the leading product in this market, with 2001 sales of approximately $1.05 billion in the United States. In January 2002, Amgen launched Neulasta, an extended-release version of Neupogen. Immunex's 2001 sales for Leukine were $109 million.

Entry into the neutrophil regeneration factor market requires lengthy preclinical and clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the Food and Drug Administration (''FDA''). Clinical development and FDA approval can extend from 6 to 10 years and cost over $200 million. The FDA must approve all phases of development, including extensive preclinical and clinical work. The most significant barriers to entry include technical, regulatory, patent, clinical and production barriers. No company can reach advanced stages of development

in the relevant market without: (1) Clinical trial expertise; (2) patent rights sufficient to provide the company with reasonable assurances of freedom to operate; (3) commercial scale product manufacturing expertise and capacity; and (4) regulatory approvals.

The proposed merger of Amgen and Immunex would cause significant anticompetitive effects in the U.S. neutrophil regeneration market by eliminating actual, direct, and substantial competition between the only two firms in the market. As a result, cancer patients that need these drugs would likely pay higher prices for neutrophil regeneration factors.

The proposed Consent Order maintains competition in the market for neutrophil regeneration factors by requiring that Immunex sell its Leukine business to Schering so that Schering can maintain the present competition against Amgen as well as the continued research and development of Leukine for future competition.

TNF Inhibitors

TNF is a cytokine that promotes the inflammation of human tissues. TNF inhibitors may be used to prevent the binding of TNF proteins with TNF receptors, thereby blocking the triggering of the inflammation cascade. TNF inhibitors are used primarily to treat rheumatoid arthritis, Crohn's disease, and psoriatic arthritis, but they also are being examined for a host of other autoimmune diseases. Annual U.S. sales of TNF inhibitors total approximately $1.4 billion.

The market for TNF inhibitors is highly concentrated. Immunex, which makes Enbrel, and Johnson & Johnson (''J&J''), which makes Remicade, are the only companies with TNF inhibitors on the market. In 2001, Immunex sold over $760 million of Enbrel in the United States and Canada, while Remicade accounted for the rest of the market in the United States. There are only three other companies with TNF inhibitors in clinical development in the United States. Amgen has a TNF inhibitor similar to Enbrel in clinical development that it expects to launch in 2005. Abbott recently submitted a Biologic License Application to the FDA for its D2E7 product. Pharmacia and Celltech are jointly in Phase II trials for their TNF inhibitor, CDP870. Additionally, Serono is developing a TNF inhibitor for use in Europe, but it does not possess the patent rights necessary to market the product in the United States.

New entry into the research, development, manufacture, and sale of TNF inhibitors is difficult, expensive, and time-consuming. As with other pharmaceutical markets, entry requires identifying a preclinical compound, performing animal safety tests, clinically developing the product in humans, securing FDA approval of commercial scale production facilities, and obtaining FDA approval to market the drug in the United States. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture, and sell a TNF inhibitor. De novo entry has been estimated to take from 8 to 10 years and cost over $400 million. New entry sufficient to deter or counteract the anticompetitive effects of the proposed merger would not occur in a timely manner.

The proposed merger of Amgen and Immunex would cause significant anticompetitive effects in the U.S. TNF inhibitor market by eliminating potential competition from Amgen's TNF inhibitor in development. Immunex and Amgen are the only two firms that market or are developing soluble TNF receptor products in the United States and two of only five firms that are developing any type of TNF inhibitor for the U.S. market. As a result of the merger, consumers of these drugs would likely pay higher prices and have fewer alternatives for TNF inhibitors for the treatment of rheumatoid arthritis and other diseases.

The proposed Consent Order maintains competition in the TNF inhibitor market by requiring that Amgen license certain patents to Serono, a Swiss biotechnology company with a soluble TNF inhibitor in clinical development that otherwise likely would not be sold in the United States due to blocking patents held by Amgen. This license would assure Serono that it has the freedom of operation necessary to market its TNF inhibitor in the U.S. Amgen retains the rights to pursue development of its TNF inhibitor either as a menotherapy or in combination with an IL–1 inhibitor.

IL–1 Inhibitors

IL–1 is another cytokine that promotes the inflammation of human tissues. IL–1 inhibitors prevent the binding of IL–1protein with IL–1 receptors, thereby blocking the triggering of the inflammation cascade. IL–1 inhibitors are used to treat rheumatoid arthritis.

The market for IL–1 inhibitors is highly concentrated. Amgen's Kineret, approved by the FDA in November of 2001, is the only IL–1 inhibitor on the U.S. market. Sales to date have exceeded $2.4 million. Immunex and Regeneron are the only other companies with IL–1 inhibitors in clinical trials in the United States. Regeneron's development and commercialization of its IL–1 Trap, however, may be delayed or foreclosed by patents owned by Immunex. It appears that Immunex is likely to succeed in its efforts to preclude Regeneron's successful commercializaiton of its IL–1 Trap product through patent infringement litigation for the following reasons: (1) Immunex has indicated that it will seek to block Regeneron by using patent litigation; (2) Regeneron has indicated that such litigation, even were it to yield an outcome favorable to Regeneron, could foreclose its ability to commercialize its IL–1 Trap; and (3) the likelihood of threatened patent litigation by Immunex will jeopardize and could effectively preclude commercialization of Regeneron's IL–1 Trap.

New entry into the research, development, manufacture, and sale of IL–1 inhibitors is difficult, expensive, and time-consuming. As with other pharmaceutical markets, entry requires identifying a preclinical compound, perforning animal safety tests, clinically developing the product in humans, securing FDA approval of commercial scale production facilities, and obtaining FDA approval to market the drug in the United States. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture, and sell an IL–1 inhibitor. *De novo* entry has been estimated to take between 6 to 10 years and cost over $200 million. New entry sufficient to deter or counteract the anticompetitive effects of the merger would not occur in a timely manner.

The proposed merger of Amgen and Immunex would cause significant anticompetitive effects in the U.S. IL–1 inhibitor market by eliminating Amgen's most significant (and likely only) potential competitor, Immunex. By consolidating the IL–1 patents of both companies, Amgen would be more likely to use its combined patents to block Regeneron from marketing an IL–1 inhibitor. Furthermore, Amgen and Immunex are the only companies actively engaged in the development of TNF/IL–1 combination therapies, which may prove more efficacious for the treatment of rheumatoid arthritis in many patients than using either drug alone. The proposed merger, therefore, is likely to lead to unilateral anticompetitive effects in the IL–1 inhibitor market by eliminating potential competition between Amgen and Immunex as well as the ongoing research and development competition between the companies.

The proposed Consent Order remedies the merger's anticompetitive effects by requiring that Immunex license certain patents to Regeneron, given Regeneron the freedom of operation necessary to bring its IL–1 Trap product to the market and compete against Amgen in this market.

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

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 02–18702 Filed 7–23–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities; Proposed Collections; Comment Request

The Department of Health and Human Services, Office of the Secretary will periodically publish summaries of proposed information collections projects and solicit public comments in compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690–6207.

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 (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.

1. *HHS Acquisition Regulation (HHSAR) Part 342—Contract Administration—0990–0131—Extension with no change*—HHSAR 342.7103 requires reporting information when a cost overrun is anticipated. The information is used to determine if a proposed overrun is reasonable. *Respondents:* State or local governments, business, or other for-profit, non-profit institutions, small business; *Number of respondents:* 215; *Average burden per response:* 20 hours; *Total burden:* 4,300 hours.

2. *HHS Acquisition Regulations (HHSAR Part 333 Disputes and Appeals—0990–0133—Extension with no change*—The Litigation and Claims clause is needed to inform the government of actions filed against government contracts. *Respondents:* State or local governments, business or other for-profit institutions, small business; *Number of respondents:* 86; *Average burden per response:* 30 minutes; *Total burden:* 43 hours.

3. *HHS Acquisition Regulation (HHSAR) Part 332—Contract Financing—0990–0134—Extension with no change*—The requirements of HHSAR Part 332 are needed to ascertain costs associated with certain contracts so as to timely pay contractors. *Respondents:* State or local governments, small businesses; *Number of respondents:* 226; *Average burden per response:* one hours; *Total burden:* 226 hours.

4. *HHS Acquisition Regulation (HHSAR) Part 324—Protection of Privacy and Freedom of Information—0990–0136—Extension with no change*—The confidentiality of information requirements are needed to prevent improper disclosure of confidential data. *Respondents:* State of local governments, business or other for-profit, non-profit institutions, small businesses; *Number of respondents:* 638; *Average burden per response:* 8 hours; *Total burden:* 5,104 hours.

5. *HHS Acquisition Regulation (HHSAR) Part 316—Types of Contracts—0990–0138—Extension with no change— The negotiated Overhead Rate*—Fixed clause is needed since fixed rates are authorized by OMB Circular and a clause is not provided in the Federal Acquisition Regulation (FAR). *Respondents:* non-profit institutions; *Number of respondents:* 520: *Average burden per response:* 10 hours; total burden: 5,200 hours.

6. *Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments—0990–0169—Extension with no change*—Pre-award, post-award, and subsequent reporting and recordkeeping requirements are necessary to award, monitor, close out and manage grant programs, ensure minimum fiscal control and accountability for Federal funds and deter fraud, waste and abuse. *Respondents:* State and local governments; *Number of respondents:* 4,000; *Average burden per response:* 70 hours; *Total burden:* 280,000 hours.

7. *HHS Acquisition Regulation (HHSAR) Part 370—Special Programs Affecting Acquisition—0990–0129—Extension with no change*—Establishes requirements for the accessibility of meetings, conferences, and seminars to persons with disabilities; establishes requirements for Indian Preference in employment, training and subcontracting opportunities. *Respondents:* State or local governments, businesses or other for-profit, non-profit institutions, small businesses; *Burden Information about Accessibility of Meetings—Annual number of respondents:* 335; *Average burden per response:* 10 hours; *Total annual number of respondents:* 932; *Average burden per response;* 8 hours; *Total annual burden:* 7,456 hours—*Total Burden:* 10,806 hours.

8. *HHS Acquisition Regulation (HHSAR) Part 352—Solicitation Provisions and Contract Clauses—0990–0130—Extension with no change*—The Key Personnel clause in HHSAR 352.27–5 requires contractors to obtain approval before substituting key personnel which are specified in the contract. *Respondents:* State or local governments, businesses or other for-profit, non-profit institutions, small businesses; Total number of *respondents:* 1,921; *Average burden per response:* 2 hours; *Total burden:* 3,842 hours.

Send comments to Cynthia Agents Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, SW., Washington DC, 20201. Written comments should be received within 60 days of this notice.

Dated: July 16, 2002.

Kerry Weems,

Deputy Assistant Secretary, Budget.

[FR Doc. 02–18622 Filed 7–23–02; 8:45 am]

BILLING CODE 4151–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Request for Measures of Patients' Hospital Care Experiences

AGENCY: Agency for Healthcare Reserach and Quality (AHRQ), HHS.

ACTION: Notice of Request for measures.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is soliciting the submission of instruments measuring patients' experience with the