records management inspections and its role as Archivist.

h. Disclosure to contractors, grantees or volunteers performing or working on a contract, service, grant, cooperative agreement, or job for the Board.

**Disclosure to consumer reporting agencies:**

Not applicable.

**Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:**

**Storage:**Records are maintained in paper and electronic format.

**Retrievability:** Electronically–stored information may be retrieved based on name, social security number, passport or visa number, or date of birth.

**Safeguards:** Only authorized personnel will have access to this information. Access to information derived from law enforcement data bases will be extremely limited.

**Retention and disposal:** Information in this system of records will be destroyed two years after the date the individual is admitted to the Board's premises.

**System manager(s) and address:**

Billy Sauls, Chief of Uniform Security, Management Division, Board of Governors of the Federal Reserve System, 20th and Constitution Avenue, NW., Washington, DC 20551.

**Notification procedure:**

Inquiries should be sent to the Secretary of the Board, Board of Governors of the Federal Reserve System, 20th and Constitution Avenue, NW., Washington, DC 20551. The request should contain the individual's name, date of birth, Social Security or passport number, and approximate date of record.

**Record access procedures:**

Same as ''Notification procedure'' above.

**Contesting record procedures:**

Same as ''Notification procedure'' above.

**Record source categories:**

Information will be gathered primarily from the individual who wishes to enter the Board's premises. Additional information may be gathered from law enforcement data bases where appropriate.

**Systems exempted from certain provisions of the act:**

This system is exempt from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2).

By order of the Board of Governors of the Federal Reserve System, June 27, 2002.

**Jennifer J. Johnson,**

*Secretary of the Board.*

[FR Doc. 02–16724 Filed 7–2–02; 8:45 am]

**BILLING CODE 6210–01–S**

## FEDERAL TRADE COMMISSION

**[File No. 011 0132]**

## Biovail Corporation and Elan Corporation, plc; 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 July 29, 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:** Joseph Simmons or Randall Marks, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–3300 or 326–2571.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 28 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 June 27, 2002), on the World Wide Web, at *http://www.ftc.gov/os/2002/06/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 To Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Biovail Corporation (''Biovail'') and Elan Corporation, plc (''Elan''), settling charges that the two companies illegally agreed to restrain competition in the market for generic Adalat CC. The Commission has placed the proposed consent order on the public record for thirty days to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by either Biovail or Elan that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

*Background*

Biovail is a Canadian manufacturer of branded and generic pharmaceutical products. Elan is an Irish manufacturer of branded and generic pharmaceutical products. Biovail and Elan are the only two sellers of generic forms of Adalat CC (''generic Adalat''), a once-a-day antihypertension medication. No other company has even sought Food and Drug Administration (''FDA'') approval to sell a 30 mg or a 60 mg dosage form of generic Adalat. Bayer AG (''Bayer'') manufactures branded Adalat CC. In 1999, before the entry of generic equivalents to Adalat CC, Bayer's United States sales of the 30 mg and 60 mg doses of Adalat CC were in excess of $270 million.

Biovail was the first to file an Abbreviated New Drug Application (''ANDA'') for FDA approval on the 60 mg dosage, and Elan was the first to file an ANDA for FDA approval on the 30 mg dosage. Thus, Elan had 180 days of exclusivity for the 30 mg product upon receiving final FDA approval, and Biovail had the 180-day exclusivity on the 60 mg product upon receiving final FDA approval. Each was the second to file on the other dosage.

In October 1999, after both Biovail and Elan (hereinafter sometimes referred to as ''Respondents'') had filed for FDA approval of their 30 mg and 60 mg generic Adalat products, they entered into an agreement involving all

four of their generic Adalat products. That agreement (the ''Agreement''), and the Respondents' conduct arising out of that Agreement, are the subject of the Commission's complaint. The complaint alleges that, by entering the Agreement, Respondents illegally created market power in the United States market for sales of 30 mg and 60 mg dosages of generic Adalat. There is little prospect of new entry in the near future, because no other companies have applied for FDA approval of a 30 mg or a 60 mg generic Adalat product.

*The Challenged Conduct*

Under the Respondents' Agreement, Elan appointed Biovail as the exclusive distributor of Elan's 30 mg and 60 mg generic Adalat products. At the time of the Agreement, neither Elan nor Biovail distributed its own generic drugs in the United States. Teva Pharmaceuticals, Inc. (''Teva''), a distributor of some of Biovail's products, participated in the negotiations leading up to the Agreement. The Agreement provided that Biovail appoint Teva to sub-distribute Elan's 30 mg generic Adalat product in the United States. With respect to Elan's 60 mg product, the Agreement provided that, upon notice from Elan that Elan's 60 mg product was ready for commercial launch, Biovail would appoint either Teva or another company as a sub-distributor of that product. The Agreement has a minimum term of 15 years.

The FDA approval Elan's mg generic Adalat product in March 2000 and its 60 mg product in October 2001. It approved Biovail's 30 mg and 60 mg generic Adalat products in December 2000. Biovail began selling Elan's 30 mg product immediately after receiving final FDA approval. Biovail began selling its own 60 mg product through Teva immediately after the FDA gave final approval to that product. Neither Elan's 60 mg product nor Biovail's 30 mg product, however, has ever been launched commercially. Thus, although two 30 mg generic Adalat products and two 60 mg generic Adalat products have had FDA approval for many months, consumers can purchase only one product at each strength.

The complaint alleges that, in exchange for the right to distribute Elan's products and share in the profits of those products, Biovail agreed to make specified payments to Elan. To date, Biovail has paid Elan approximately $33 million in connection with its distribution of Elan's 30 mg generic Adalat product, and $12.75 million in connection with the right to distribute Elan's 60 mg generic Adalat product.

As the complaint alleges, the Agreement gave Biovail substantial incentives not to launch its own 30 mg product. Although Biovail has had final FDA approval to market its 30 mg product for over one year, and the Agreement purports to require Biovail to use ''reasonable commercial endeavors'' to launch that product ''with reasonable dispatch,'' Biovail has not yet launched that product. Biovail's launch of its own 30 mg product could be expected to cause a significant reduction in the price of Elan's incumbent 30 mg product, and generate for Elan's product lower total profits, which Biovail shares with Elan. For the same reasons, the Agreement diminished Biovail's incentives to exercise maximum efforts at eliminating the technological obstacles, if any, that Biovail asserts have impeded its ability to launch a self-manufactured 30 mg product. Elan also does not have any incentive to enforce the Agreement's provision requiring that Biovail use reasonable efforts to launch its 30 mg product in competition with Elan's product.

Similarly, the complaint alleges that the Agreement gave Elan substantial incentives not to launch its 60 mg product. Under the Agreement, in exchange for receiving a large up-front payment, Elan, in effect, stood to receive no royalties upon launch of its 60 mg product, until that product generated certain profits for Biovail. It would take several years of sales before Elan's 60 mg product would generate such profits, and once that triggering event happened, Elan's royalty was to be only 6% of profits. Accordingly, the complain alleges that the Agreement compensated Elan for its 60 mg product up-front and pre-entry, while substantially diminishing that product's value to Elan thereafter. The Agreement also diminished Elan's incentives to exercise maximum efforts at eliminating any technological obstacles to launching its 60 mg product, if any, that Elan has asserted to exist. Moreover, neither Elan nor Biovail had any financial incentives to enforce the provision requiring launch of Elan's 60 mg product. As with the launch of Biovail's 30 mg product, Respondents knew that Elan's launch of its own 60 mg product could be expected to cause a reduction in the price of Biovail's incumbent 60 mg product by a significant amount and generate lower total profits for Biovail's product. It was in Bilvail's strategic interest, therefore, for Elan not to launch its 60 mg products.

The complaint further alleges that even its Bilvail had launched its 30 mg product and Elan had launched its 60 mg product, the Agreement allows Biovail to control or influence pricing and other competitive features of both its and Elan's 30 mg and 60 mg generic Adalat products. Biovail was thus in a position to profit by suppressing competition between its and Elan's products.

For the above reasons, the complaint alleges that Respondents' Agreement is an agreement not to compete between the only two producers of the 30 mg and 60 mg generic Adalat products. As a result, Teva, Biovail's distributor, is the only firm selling generic Adalat to consumers in the United States, and consumers have had access to only one of two approved generic Adalat products at each strength. Moreover, the Agreement is not justified by an countervailing efficiency.

*The Proposed Order*

The proposed order remedies the Respondents' anticompetitive conduct by requiring them to end their anticompetitive Agreement and barring them from engaging in similar conduct in the future. It maintains supply of the incumbent generic Adalat products while Respondents unwind their anticompetitive Agreement and eliminates the anticompetitive obstacles to entry of a second 30 mg and a second 60 mg generic Adalat product.

Paragraph I of the proposed order contains definitions, one of which defines the ''Adalat CC Agreement'' as the ''License, Distribution & Supply Agreement'' covering generic Adalat that Biovail and Elan executed on October 4, 1999, and all modifications and amendments thereto. We discuss other definitions below, as needed to explain the substantive provisions of the proposed order.

Paragraph II of the proposed order is a core provision, prohibiting Biovail or Elan from repeating the instant conduct by entering anticompetitive price, output, or distribution agreements with other generic drug companies. This provision targets agreements between either Respondent and other persons concerning a generic drug for which both parties to the agreement have filed for FDA approval of an ANDA referencing the same pioneer drug product. It aims to prohibit agreements between competing generic drug manufacturers that restrict the marketing of competing generic drugs.

Paragraph III of the proposed order requires Biovail and Elan to terminate their agreement on generic Adalat no later than the date on which the order becomes final. Paragraph 13 of the Agreement Containing Consent Order required them to start the termination process upon their execution of that

document. The proviso to Paragraph III allows Biovail and Elan to resolve financial issues connected to the termination of their agreement on generic Adalat on mutually agreeable terms; however, they cannot resolve those financial issues by using sales, revenues, or profits generated by generic Adalat or any other drug product, or by transferring rights connected to any drug product. This limitation is intended to ensure that, in resolving the financial issues, Respondents do not perpetuate the anticompetitive effects of the Agreement by continuing the entanglements between them on generic Adalat or on other drug products.

Paragraph IV of the proposed order prohibits Elan from distributing its generic Adalat product through Teva. This prohibition is necessary because Biovail and Teva have a longstanding commercial relationship, whereby Teva distributes some of Biovail's product. Forbidding Elan from distributing this generic Adalat products through Teva will minimize the risk of inappropriate information exchange among Biovail, Elan, and Teva regarding generic Adalat, by eliminating any legitimate reason for all three companies to discuss their marketing of the products. Thus, it will help ensure that the termination of the Agreement fully restores the proper competitive incentives for each company.

The proviso to Paragraph IV requires Elan to supply Teva, through Biovail, with Elan's 30 mg product, until the earlier of Biovail's launch of its own 30 mg product or May 31, 2003 (the ''Interim Supply Agreement''). This provision eliminates any disruption of supply of the 30 mg product to consumers while Elan makes alternate arrangements for the distribution of its products. Once Elan begins to distribute its own product through an independent distributor, the Interim Supply Agreement will assure that consumers have access to two generic 30 mg Adalat products. The Interim supply Agreement may continue for up to a year, to give consumers the continued benefit of two 30 mg generic Adalat products while Biovail solves its purported manufacturing difficulty. Biovail has assured the Commission that it expects to overcome any manufacturing problems it has and launch its 30 mg generic Adalat product within a year. (Paragraph V further addresses Biovail's launch of its own 30 mg product, as we discuss below.)

Paragraph IV prohibits Elan from charging Biovail more than Elan's ''Cost'' for the product. Paragraph I of the proposed order defines ''Cost'' to mean Elan's actual manufacturing cost. The cost definition is narrow, to minimize Elan's ability to profit from the Interim Supply Agreement through manipulation of the definition. Preventing Elan from profiting by supplying Biovail with the Elan 30 mg generic Adalat product gives Elan a strong incentive to launch its own 30 mg product through an indecent distributor as quickly as possible. Only through that launch will Elan begin to earn a profit on its 30 mg product. Because, under the Interim Supply Agreement, Biovail will receive Elan's 30 mg product at Elan's 30 mg product at Elan's manufacturing cost, Biovail will be in the same competitive position with respect to the cost of the 30 mg product as will Elan. In addition, Biovail will have to compete with Elan's new distributor to gain and maintain market share. Thus, the narrow cost definition will also give consumers the benefit of immediate price competition between the 30 mg product marketed by Teva and the 30 mg product marketed by Elan's independent distributor.

Paragraph V of the proposed order require Elan to use best efforts to launch its 30 mg and 60 mg generic Adalat products as promptly as possible through a distributor other than Teva. It also requires Biovail to use best efforts to manufacture and distribute its 30 mg Adalat product, and to use best efforts to continue to manufacture and distribute its 60 mg generic Adalat product through a distributor other than Elan's generic Adalat distributor. Paragraph V.C states that the purpose of these requirements is to restore competitive incentives in the market for generic Adalat, and to remedy the lessening of competition resulting from the anticompetitive practices alleged in the Commission's complaint. This provision covers all four generic Adalat products, to ensure that Biovail and generic market their 30 mg and 60 mg products through separate distributors. The proposed order defines ''Launch'' to require Biovail and Elan to deliver commercial quantities of their generic Adalat products to a viable pharmaceutical distributor pursuant to a commercially reasonable, multi-year contract. This definition will ensure that the launch of Elan's 60 mg product and of Biovail's 30 mg product is on a competitive scale.

The Commission will closely monitor Respondents' efforts to market their products. To facilitate this, the proposed order includes reporting requirements. Paragraph VIII requires Biovail and Elan to submit to the Commission verified written reports detailing each of their efforts to comply with the proposed order. Biovail and Elan must submit these reports every thirty days until they have complied with the proposed order.

Paragraph VI of the proposed order requires Biovail and Elan to give the Commission notice of two types of agreements with other pharmaceutical manufacturers. First, Paragraph VI.A requires Biovail and Elan to give notice of agreements where, at the time of the agreement, the parties to the agreement each own, control, or license another product that is in the same ''Therapeutic Class'' as the product covered by the agreement. (The proposed order defines ''Therapeutic Class'' as a class of drugs categorized by the Unified System of Classification contained in the most recent version of the IMS Health Incorporated publication Market Research Database: Product Directory.) Aa proviso excepts from the reporting requirement agreements that only transfer ''Drug Delivery Technology'' in exchange for a commercially reasonable cash royalty not to exceed drive per cent of revenue. The proposed order defines ''Drug Delivery Technology'' to mean technology that controls the release rate, or enhances the absorption or utilization of a pharmaceutical compound.)

Second, Paragraph VI.B requires Biovail and Elan to give notice of agreements involving a product for which one party to the agreement has an ANDA that references a New Drug Application (''DNA'') that the other party owns, controls, or licenses. The notification provisions contained in Paragraph VI are necessary, because the core prohibition in Paragraph II only reaches agreements involving ANDAs that reference the same branded drug. Paragraph VI ensures that the Commission will receive notice of potentially anticompetitive agreements not covered by Paragraph II (*i.e.*, agreements involving potentially competitive branded products, and agreements regarding a brand product and its generic equivalent.)

Paragraphs VII, VIII, IX, and X of the proposed order contain reporting and other standard Commission order provisions designed to assist the Commission in monitoring compliance with the order. Paragraph XI provides that the order will expire in ten years.

*Opportunity for Public Comment*

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

containing the proposed order or make the proposed order final.

By accepting the proposed order subject to final approval, the Commission anticipates that the competitive issues alleged in the complaint will be resolved. The purpose of this analysis is to facilitate public comment on the agreement. It is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 02–16711 Filed 7–2–02; 8:45 am]

**BILLING CODE 6750–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[60Day–02–67]**

### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

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. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

*Proposed Project:* Descriptive Epidemiology of Missed or Delayed Diagnosis for Conditions Detected by Newborn Screening—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

**Background**

Every state in the United States and Washington DC has a public health program to test newborn babies for congenital metabolic and other disorders through laboratory testing of dried blood spots. These programs screen between 4 and 30 different conditions including phenylketonuria (PKU) and congenital hypothroidism, with testing performed in both state laboratories and private laboratories contracted by state health departments. The screening process or system is broader than the state public health newborn screening program, which is composed only of the laboratory and follow-up personnel. It involves the collection of blood from a newborn, analysis of the sample in a screening laboratory, follow up of abnormal results, confirmatory testing and diagnostic work up.

Parents, hospitals, medical providers including primary care providers and specialists, state laboratory and follow-up personnel, advocates, as well as other partners such as local health departments, police, child protection workers and courts play important roles in this process. Most children born with metabolic disease are identified in a timely manner and within the parameters defined by the newborn screening system of each state. These children are referred for diagnosis and treatment. However, some cases are not detected at all or the detection comes too late to prevent harm. These ''missed cases'' often result in severe morbidity such as mental retardation or death.

In this project, we will update and expand a previous epidemiological study of missed cases of two disorders published in 1986. We will assess the number of cases of each disorder missed, the reasons for the miss and legal outcomes, if any. The reasons for the miss will be tabulated according to which step or steps of the screening process it occurred. Data will be collected by asking state public health laboratory directors, newborn screening laboratory managers, follow up coordinators, lawyers and parent groups with an interest in newborn screening for information regarding missed cases. An estimated 250 subjects will be requested to complete a short questionnaire that asks for information regarding the details of any missed cases of which they are aware. Follow-up telephone calls may be necessary to clarify responses. There is no cost to the respondents.

The survey will highlight procedures and actions taken by states and other participants in newborn screening systems to identify causes of missed cases and to modify policies and procedures to prevent or minimize recurrences. The information gleaned from this study may be used to help craft changes in the screening protocols that will make the process more organized and efficient and less likely to fail an affected child. Further, it is not clear that there is a systematic assessment of missed cases on a population basis; this project will seek to identify procedures for routine surveillance of missed cases.

| Respondents | Number of respondents | Number of responses/respondents | Average burden/response (in hours) | Total burden (in hours) |
|---|---|---|---|---|
| Questionnaire | 125 | 2 | 15/60 | 62 |
| Telephone Follow-up | 75 | 2 | 10/60 | 24 |
| Total | ..... | ..... | ..... | 86 |