Trans #	Acquiring	Acquired	Entities
20020617	Alltrista Corporation	Bligh Limited	Tilia Canada, Inc. Tilia International, Inc. Tilia, Inc.
20020620	Fox Paine Capital Fund, L.P	Duke Energy Corporation	The HENS Companies.
20020621	Duke Energy Corporation	Fox Paine Capital Fund, L.P	The HENS Companies.
20020622	Launchworks, Inc	Viasource Communications, Inc	Viasource Communications, Inc.
20020624	On Assignment, Inc	Health Personnel Options Corporation	Health Personnel Options Corporation.
Transactions Granted Early Termination—04/08/2002			
20020543	Identix Incorporated	Visionics Corporation	Visionics Corporation.
20020599	Tricon Global Restaurants, Inc	Yorkshire Global Restaurants, Inc	Yorkshire Global Restaurants, Inc.
20020623	Avanex Corporation	Oplink Communications, Inc	Oplink Communications, Inc.
Transactions Granted Early Termination—04/10/2002			
20020552	Philip F. Anschutz	Edison International	Southern California Edison Company.
20020613	Cleco Corporation	Mirant Corporation	Perryville Energy Partners, L.L.C.
20020619	The Reader's Digest Associates, Inc	Madison Dearborn Capital Partners II, L.P	Reiman Holding Company, LLC.
Transactions Granted Early Termination—04/12/2002			
20020634	Don Tyson	Millard Refrigerated Services, Inc	Millard Refrigerated Services, Inc.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, or Chandra L. Kennedy, Contact Representatives. Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580. (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 02–10577 Filed 4–29–02; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[File No. 011 0094]

Biovail 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 May 23, 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 Simons or Bradley Albert, Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, DC 20580, (202) 326–3300 or 326–3670.

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 April 23, 2002), on the World Wide Web, at ''*http://www.ftc.gov/os/2002/04/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 e-mail 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, settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent with the U.S. Food and Drug Administration. The Commission has placed the proposed consent order on the public record for thirty days in order 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 Biovail Corporation that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background

Biovail Corporation is a Canadian manufacturer of branded and generic pharmaceutical products, including Tiazac. Tiazac, a once-a-day diltiazem-based prescription drug that is at issue in this case, is used to treat high blood pressure and to decrease the occurrence

of chronic chest pain. In 2000, Tiazac's sales reached almost $200 million, accounting for 38 percent of Biovail's gross sales.

Andrx Pharmaceuticals, Inc., a Florida-based company that develops generic versions of branded pharmaceuticals, was the first company to submit an application to the U.S. Food and Drug Administration (''FDA'') to make and sell a generic version of Tiazac. Andrx's application to the FDA included a certification asserting that its generic product would not infringe any patent claiming Tiazac. At that time, the only patent known to claim Tiazac was U.S. Patent Number 5,529,791 (''the ''791 patent''), which covers aspects of Tiazac's once-a-day formulation.

As in several recent Commission matters, the facts of this case are set against the backdrop of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as ''the Hatch-Waxman Act.'' Congress enacted the Hatch-Waxman Act to facilitate the entry of lower priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs. In particular, the Hatch-Waxman Act established certain rights and procedures in situations where a company seeks approval from the FDA to market a generic product prior to the expiration of a patent or patents relating to the branded drug upon which the generic is based.

A generic drug is a pharmaceutical product that the FDA has determined to be bioequivalent to a branded drug. Generic drugs are chemically identical to their branded counterparts, but they typically are sold at substantial discounts from the branded drug's price. A Congressional Budget Office Report estimates that U.S. consumers saved an estimated $8–10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the branded product.[1]

Under the provisions of the Hatch-Waxman Act, a company seeking approval from the FDA to market a new drug must file a New Drug Application (''NDA'') demonstrating the safety and efficacy of its product. As part of this process, the NDA applicant also is required to submit to the FDA information on any patent claiming the approved drug and for which a claim of patent infringement could reasonably be asserted against another party. The FDA then lists the approved drug and its related patents in a publication entitled ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' commonly known as the ''Orange Book.''

The Hatch-Waxman Act also allows the listing of patents that are issued by the U.S. Patent and Trademark Office after an NDA has been approved.[2]

In order to receive FDA approval to market a generic version of a branded drug, a company must file an Abbreviated New Drug Application (''ANDA'') demonstrating that its product is bioequivalent to its branded counterpart. As part of the ANDA application process, the ANDA applicant also must provide a certification to the FDA regarding its generic product and any patents listed in the Orange Book that claim the reference branded drug. Under one form of certification, known as a ''Paragraph IV certification,'' the ANDA applicant certifies that the patents listed in the Orange Book either are invalid or will not be infringed by the manufacture, use, or sale of the drug products for which the ANDA is submitted.

The Hatch-Waxman Act further provides that notice of the Paragraph IV certification must be provided to each patent owner and the NDA holder for the listed drug. After receiving notice of a Paragraph IV certification, if the branded drug owner does not initiate a patent infringement suit within forty-five days, then the FDA's review and generic approval process may proceed according to the FDA's schedule. If, however, a patent infringement suit is filed within the forty-five day window, the FDA's approval of the ANDA is automatically stayed until the earliest of: (1) The date the patents expire; (2) a final determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of thirty months from the receipt of notice of the Paragraph IV certification (the ''30-month stay'').

Andrx filed the first ANDA for a generic version of Tiazac in June 1998. At that time, it provided a Paragraph IV certification to the FDA regarding the only patent then claiming Tiazac, the '791 patent. Within forty-five days of receiving Andrx's notice of certification, Biovail filed a patent infringement lawsuit, alleging that Andrx's generic Tiazac product would infringe the '791 patent. This lawsuit triggered a 30-month stay of final regulatory approval of Andrx's ANDA, which was to expire on February 26, 2001 (or earlier, if an appellate court decision was granted in Andrx's favor before that date).

On March 6, 2000, the U.S. District Court presiding over the patent infringement suit found that Andrx's product did not infringe the '791 patent.[3] Biovail appealed this decision to the U.S. Court of Appeals for the Federal Circuit. On September 29, 2000, while the appeal was still pending, the FDA tentatively approved Andrx's ANDA and informed Andrx that it would be eligible to receive final FDA approval upon expiration of the 30-month stay. This stay would have expired on February 13, 2001, the day the Federal Circuit affirmed the district court's ruling that Andrx's product did not infringe Biovail's '791 patent.

Before the Federal Circuit issued its decision, however, Biovail, on January 8, 2001, listed a second patent in the Orange Book as claiming Tiazac. Biovail acquired this patent, U.S. Patent No. 6,162,463 (''the '463 patent''), from DOV Pharmaceuticals, Inc., of New Jersey, through an exclusive licensing arrangement that also included plans to jointly develop new diltiazem products using the '463 patent. Because of this listing, Andrx was required to submit a second Paragraph IV certification asserting non-infringement of the '463 patent. After receiving Andrx's certification, Biovail filed a second patent infringement suit, triggering a second 30-month stay of the final approval of Andrx's ANDA, and further delaying the potential entry of Andrx's generic Tiazac product.

The Challenged Conduct

The Commission's complaint alleges that Biovail acquired exclusive rights to the '463 patent from DOV Pharmaceuticals, Inc., for the purpose of listing it in the FDA's Orange Book and thereby blocking Andrx's entry into the Tiazac market.

Two days after the U.S. Patent and Trademark Office issued the '463 patent, Biovail met with DOV to discuss a potential licensing agreement. Biovail sought to complete an exclusive licensing agreement with DOV by no later than January 19, 2001, the last date on which it could list the patent in the Orange Book and still be eligible to trigger Hatch-Waxman provisions that could result in a 30-month stay. Biovail listed the '463 patent in the Orange Book on January 8, four days before it actually completed the exclusive license agreement with DOV.

In its certification to the FDA supporting the listing of the patent, Biovail attested that the '463 patent claimed FDA-approved Tiazac.

[1] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at xiii & 13 (July 1998).

[2] 21 U.S.C. § 355(c)(2).

[3] *Biovail Corp. Int'l* v. *Andrx Pharm. Inc.,* 2000 WL 33354427 (S.D.. Fla. March 6, 2000).

According to the complaint, however, Biovail was aware that the '463 patent did not claim the formulation of Tiazac that it had been marketing. The product described in the '463 patent contains at least 1 percent of uncoated or ''free'' immediate-release diltiazem, in addition to extended-release diltiazem in the form of coated beads. By contrast, the only form of Tiazac that Biovail has ever sold contains only negligible amounts—that is, well below 1 percent—of uncoated immediate-release diltiazem. Accordingly, Biovail did not need the '463 patent in order to make or sell its existing FDA-approved formulation of Tiazac, and it could have continued to do so without infringing the '463 patent. Moreover, in prosecuting the patent before the U.S. Patent and Trademark Office, Dr. Lippa of DOV was required to distinguish the '463 patent from the prior art—including Biovail's Tiazac—before the patent examiner approved the patent. This suggests that the '463 patent could not simultaneously be valid and properly listed in the Orange Book for Tiazac.

After learning that DOV was unable to give it a license to the '463 patent because of Biovail's exclusive license, Andrx petitioned the FDA to require Biovail to de-list the '463 patent from the Orange Book. Although the FDA has publicly stated that it lacks the resources and the expertise to review patents submitted with NDAs and that it has only a limited ''ministerial role'' in listing patents,[4] a party may dispute the propriety of a patent listing, as Andrx did, by notifying the FDA. The FDA will then request that the NDA holder confirm that the listed patent information is correct. Unless the NDA holder voluntarily withdraws or amends its listing, however, the FDA will not change the patent information in the Orange Book. As one court has observed, the FDA's listing of a patent does ''not create any presumption that [a] patent was correctly listed'' in the Orange Book.[5]

On February 7, 2001, and again on February 22, 2001, the FDA, consistent with its limited ''ministerial role'' in listing patents in the Orange Book, sought confirmation from Biovail that the '463 patent was properly listed. The complaint alleges that on February 26, 2001, as a result of a court filing by Biovail in a federal lawsuit brought by Andrx to force Biovail to de-list the '463 patent,[6] the FDA learned that Biovail's position was that the '463 patent covered a new formulation of Tiazac that Biovail had developed only after it acquired and listed the '463 patent, rather than the version of Tiazac that the FDA had approved and that Biovail had been marketing. The FDA notified Biovail on March 20, 2001, that its new formulation of Tiazac was not approved by the FDA under the Tiazac NDA. Accordingly, the FDA would de-list the '463 patent from the Orange Book unless Biovail amended its certification to indicate that the patent claimed the version of Tiazac the FDA had approved.

In response to the FDA's inquiries, Biovail submitted a signed declaration stating that the '463 patent was eligible for listing in the FDA's Orange Book as claiming Tiazac. The complaint alleges that this declaration was misleading because it did not clarify whether the term ''Tiazac'' as used by Biovail meant the form of Tiazac the FDA had approved for marketing (as the FDA intended) or Biovail's revised form of the product. The FDA understood Biovail's March 26, 2001, declaration as affirming that the '463 patent covers the currently approved Tiazac product. On that basis, the FDA decided not to de-list the '463 patent from the Orange Book. According to the complaint, however, Biovail continued to assert that listing the '463 patent in the Orange Book was justified because it covers a revised form of Tiazac that Biovail believed fell within the Tiazac NDA, but which the FDA did not.

The complaint concludes that as a result of Biovail's conduct, consumers of Tiazac have been deprived of the benefits of lower-priced generic competition that might have been possible had Biovail not acquired exclusive rights to, and then listed, the '463 patent, thereby precluding the FDA from granting final approval to Andrx's generic Tiazac in February 2001.

Competitive Analysis

The complaint alleges that the relevant product market in which to assess the anticompetitive effects of Biovail's conduct is Tiazac and generic bioequivalent versions of Tiazac. Although other therapeutic agents can be used to treat high blood pressure and chronic chest pain, including several other branded and generic formulations of once-a-day diltiazem, these other therapeutic agents do not significantly constrain Tiazac's pricing. In contrast, entry of a generic bioequivalent version of Tiazac likely would result in a significant, immediate decrease in the sales of branded Tiazac, and lead to a significant reduction in the average market price paid for Tiazac and its generic bioequivalents. In fact, Biovail's own sales forecasts projected that generic Tiazac would have captured 40 percent of branded Tiazac sales within the first year alone.

The relevant geographic market in which to assess the competitive effects of Biovail's conduct is the United States, given the FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals, like Tiazac, occur on a nationwide basis.

The complaint thus alleges that, at all times relevant to this case, Biovail's market share of the relevant antitrust market has been 100 percent.

Biovail's conduct as described above, and as alleged in the complaint, violated the antitrust laws in two ways. First, Biovail's acquisition of an exclusive license to the '463 patent substantially lessened competition in the U.S. market for Tiazac and its generic equivalents. As stated in the complaint, Biovail's acquisition of the exclusive license to the '463 patent raised substantial barriers to Andrx's entry into the relevant market and gave Biovail the power to exclude competition, thereby protecting Biovail's monopoly in the Tiazac market, in violation of section 7 of the Clayton Act, 15 U.S.C. 18, and section 5 of the FTC Act, 15 U.S.C. 45.

The complaint also alleges that Biovail violated Section 5 of the FTC Act by engaging in acts that willfully maintained its Tiazac monopoly. These acts included: (a) acquiring an exclusive license to the '463 patent for the purpose of listing it in the Orange Book; (b) wrongfully listing the '463 patent in the Orange Book as claiming Tiazac, in order to be eligible for an automatic 30-month stay of FDA approval for any generic Tiazac product; and (c) giving non-responsive answers to questions raised by the FDA about the propriety of listing the '463 patent in the Orange Book, so as to avoid the possibility of de-listing. As the complaint states, Biovail's illegal monopolization raised substantial barriers to entry into the relevant market and gave Biovail the power to exclude competition. Biovail thereby deprived consumers of the benefits of lower-priced generic competition that might have been possible had the FDA not been precluded from granting final approval to Andrx's generic Tiazac. These acts and practices are anticompetitive in

[4] 59 FR 50338, 50345 (Oct. 3, 1994).

[5] *Ben Venue Labs., Inc.* v. *Norvartis Pharm. Corp.,* 10 F. Supp. 2d 446, 456 (D.N.J. 1998).

[6] The federal district court eventually rules that there is no private right of action under the Food, Drug, and Cosmetic Act for one company to require another to de-list a patent from the Orange Book. *Amdrx Pharm., Inc.* v. *Biovail Corp.,* 175 F. Supp. 2d 1362, 1373 (S.D. Fla. 2001).

nature and tendency, and constitute an unfair method of competition in violation of section 5 of the FTC Act, 15 U.S.C. 45.

The Proposed Order

The proposed order is designed to address the anticompetitive effects of Biovail's illegal conduct charged above, by requiring Biovail to divest part of its exclusive rights to the '463 patent and by providing other relief, on a prospective basis, to prevent or discourage recurrence of such conduct in the future. In essence, the proposed order:

- Requires that Biovail divest to DOV the exclusive rights to the '463 patent, as it applies for use in making any form of the currently marketed and FDA-approved Tiazac product.
- Prevents Biovail from taking any actions that would result in an additional 30-month stay of final FDA approval for a generic form of Tiazac.
- Prohibits Biovail from wrongfully listing any patents in the Orange Book in violation of applicable law.
- Requires that Biovail give the Commission prior written notice before it acquires an exclusive license to any patent that it plans to list in the Orange Book for a product for which Biovail already has an FDA-approved NDA.

By requiring that Biovail divest its exclusive rights in the ''463 patent in the ''Tiazac Field,'' that is, for use in making any form of the currently FDA-approved Tiazac, Paragraph II returns the market for Tiazac products to the status quo as it existed before the patent acquisition occurred. Paragraph II.A requires that Biovail divest to DOV its exclusive interest in the ''463 patent as it relates to the Tiazac Field. Paragraph II.B prevents Biovail from structuring the divestiture in such a way that it would be able to continue reaping the benefits of its acquisition of the patent. Paragraph II.C proscribes the creation of a confidentiality agreement that could hinder future Commission enforcement actions against Biovail under the order or the antitrust laws. Paragraph II.D prohibits Biovail from having any input into the future utilization of the patent in the Tiazac Field. Paragraph II.E prevents Biovail from participating in any lawsuits to enforce the ''463 patent in the Tiazac Field. Paragraph II.F requires Biovail to dismiss its patent infringement claim against Andrx.

Taken as a whole, Paragraph II removes Biovail's possession of exclusive rights in the ''463 patent (through which it was able to erect barriers to Andrx's potential entry), while preserving Biovail's and DOV's ability to innovate and develop new products using that same patent. Paragraph II allows Biovail to continue to use the ''463 patent, on an exclusive basis, to develop new diltiazem products that may result in the filing of an NDA with the FDA. Moreover, nothing in the paragraph prevents Biovail from holding non-exclusive rights to the ''463 patent to develop improved forms of the currently marketed Tiazac product.

If Biovail fails to complete the divestiture required in Paragraph II.A within ninety days of signing the Agreement Containing Consent Order in this matter, Paragraph III of the Proposed Order requires Biovail to enter into a trust agreement and transfer the assets set forth in Paragraph II.A to a trustee appointed by the Commission. The trustee will then have the sole and exclusive power to divest the assets required in Paragraph II.A, subject to the prior approval of the Commission. The trustee will have twelve months to accomplish the divestiture, at no minimum price, to a buyer or buyers approved by the Commission.

Paragraph IV is intended to remedy Biovail's allegedly illegal monopolization. By preventing Biovail from engaging in strategies that pharmaceutical companies have used to exploit the Hatch-Waxman Act to thwart generic entry, Paragraph IV seeks to ensure the entry of a generic Tiazac product at the earliest possible moment.

Paragraph V is intended to deter Biovail from listing patents in the Orange Book that do not actually claim the drug product at issue, and thus prevent the triggering of procedures under the Hatch-Waxman Act that could improperly block generic entry. The Commission is concerned that improper patent listings may be a recurring problem in the pharmaceutical industry, and that such listings have a significant potential to affect competition and harm consumers. NDA holders have the ability unilaterally to list patents in the Orange Book—and thus exclude potential generic competitors from entering the market and competing for up to thirty months—whether or not the patent they list actually claims the product approved under the NDA. Because the FDA views its role in listing patents as ''purely ministerial,'' and because there is no private right of action to challenge a patent listing under the Food, Drug, and Cosmetic Act,[7] or NDA holders, such as Biovail in this case, to obtain an additional thirty months free from generic competition by listing inappropriate patents in the Orange Book.

The Commission believes that the operative provisions in Paragraphs II through V of the proposed order strike an appropriate balance between Biovail's interests in acquiring patents for legitimate business purposes, such as developing new products using that intellectual property, and the Commission's intention to remedy an NDA holder's creation of barriers to generic competition through strategic patent acquisitions and the misuse of the Hatch-Waxman regulatory framework. By not imposing broad prohibitions on Biovail's ability to develop new products based on the ''463 patent, and by not preventing Biovail from legitimately acquiring and listing patents for other NDAs it may hold, the order maintains Biovail's incentive to develop and sell new drug products, while curbing the potential for Hatch-Waxman Act abuse.

Paragraph VI requires that Biovail submit written notification to the Commission before acquiring any patent or exclusive license on a patent, if Biovail also intends to seek the patent's listing in the Orange Book. Biovail will thus be free to continue acquiring intellectual property for legitimate business purposes, but the Commission will be notified in situations where there is a possibility that the acquisition of an exclusive license may serve to protect Biovail's dominant position in a relevant pharmaceutical market.

Paragraph VII sets forth the form of notice that Biovail must provide to the Commission under Paragraph VI of the order. In addition to supplying a copy of the patents to be acquired, Paragraph VII requires Biovail to provide certain other information to assist the Commission in assessing the potential competitive effect of the patent acquisition. Accordingly, the order requires Biovail to identify, among other things, the parties participating in the acquisition, the approved NDA(s) with respect to which the acquired patent will be submitted for listing in the Orange Book, and all persons who have filed an ANDA referencing the identified NDAs. In addition, Biovail must provide the Commission with copies of all transactional documents and other documents that evaluate the proposed licensing agreement.

Paragraphs VIII, IX, and X of the proposed order contain certain reporting and other standard Commission order provisions designed to assist the Commission in monitoring compliance with the order.

The order will expire in ten years.

[7] *Mylan* v. *Bristol-Myers Squibb Co.* 268 F.3d 1323, 1331–32 (Fed. Cir. 2001). See also *Andrx Pharm., Inc.* v. *Biovail Corp.,* 175 F. Supp. 2d 1362, 1373 (S.D. Fla. 2001).

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 addressed. 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. 02–10578 Filed 4–29–02; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Draft Guideline for Disinfection and Sterilization in Healthcare Facilities

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice of availability and request for public comment.

SUMMARY: This notice is a request for review of and comment on the *Draft Guideline for Disinfection and Sterilization in Healthcare Facilities, 2003*, available on the CDC website at *www.cdc.gov/ncidod/hip/dsguide.htm.* The guideline has been developed for practitioners who provide care for patients and who are responsible for monitoring and preventing infections in healthcare settings, especially those involved in sterilizing and disinfecting medical devices and surgical instruments. The guideline is intended to replace the section in *Guideline for Handwashing and Hospital Environmental Control, 1985,* that dealt with sterilization and disinfection.

DATES: Comments on the *Draft Guideline for Disinfection and Sterilization in Healthcare Facilities, 2003* must be received in writing on or before June 14, 2002.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the *Draft Guideline for Sterilization and Disinfection in Healthcare Facilities, 2003* should be submitted to the Resource Center, Attention: DSGuide, Division of Healthcare Quality Promotion, CDC, Mailstop E–68, 1600 Clifton Rd., NE, Atlanta, Georgia 30333; fax 404 498–1244; e-mail: *dsrequests@cdc.gov;* or Internet: *www.cdc.gov/ncidod/hip/dsguide.htm.*

ADDRESSES: Comments on the *Draft Guideline for Disinfection and Sterilization in Healthcare Facilities, 2003* should be submitted to the Resource Center, Attention: DSGuide, Division of Healthcare Quality Promotion, CDC, Mailstop E–68, 1600 Clifton Road, NE., Atlanta, Georgia 30333; fax 404 498–1244; e-mail: *dscomments@cdc.gov;* or Internet: *www.cdc.gov/ncidod/hip/dsguide.htm.*

SUPPLEMENTARY INFORMATION: The *Draft Guideline for Disinfection and Sterilization in Healthcare Facilities, 2003* presents a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes in healthcare settings. The guideline is intended to assist healthcare personnel in preventing infections associated with contaminated medical devices or surgical instruments and is targeted to infection control professionals, infectious disease clinicians, physicians who perform endoscopic procedures (e.g., gastroenterologists, pulmonologists), central processing technicians, sterile processing technicians, operating room nurses and technicians, manufacturers of disinfection and sterilization equipment, and manufacturers of reusable medical devices.

Part 1 of the two-part document provides information on chemical disinfectants recommended for patient-care equipment; these disinfectants include alcohol, glutaraldehyde, hydrogen peroxide, iodophors, ortho-phthalaldehyde, peracetic acid, phenolics, quaternary ammonium compounds, and sodium hypochlorite. Sterilization methods discussed include steam sterilization, ethylene oxide, hydrogen peroxide gas plasma, and liquid peracetic acid. Part 2 of the document provides consensus recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) for the practice of disinfection and sterilization in healthcare settings. Most recommendations are pertinent for the inpatient, outpatient, and home care setting, unless otherwise noted.

HICPAC was established in 1991 to provide advice and guidance to the Secretary and the Assistant Secretary for Health, DHHS; the Director, CDC; and the Director, National Center for Infectious Diseases, regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections in U.S. healthcare facilities. The committee advises CDC on guidelines and other policy statements regarding prevention of healthcare-associated infections and related adverse events.

Dated: April 24, 2002.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 02–10550 Filed 4–29–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0116]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive (VFD)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including renewal of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for distribution and use of VFD drugs and animal feeds containing VFD drugs.

DATES: Submit written or electronic comments on the collection of information by July 1, 2002.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug