

# EXHIBIT 2

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September 11, 2012

**VIA MESSENGER**

June Im, Esq.  
Federal Trade Commission  
Bureau of Competition  
601 New Jersey Avenue, N.W.  
Washington, DC 20001

Re: File No. 121-0062: ViroPharma

Dear June:

Please find enclosed 1) responses, in part, to Specifications 1, 6, 13, 15, 30, 32, and 33, 2) a list of general objections and qualifications to the Federal Trade Commission's civil investigative demand, and 3) discs containing certain documents referenced in the response.

Please let me know if you have any questions.

Sincerely,



David J. Shaw  
Associate

Enclosures

CC: Melanie Brown, Esq.

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**ViroPharma's Responses, in part, to Specifications 1, 6, 13, 15, 30, 32, and 33**

ViroPharma hereby incorporates by reference each and every objection stated in the General Objections.

**SPECIFICATION 1:** Submit one copy of each current and March 2006 ViroPharma organization chart and personnel directory for (1) top-level management; and (2) each of ViroPharma's facilities or divisions involved in any activity related to any Vancomycin Product.

**Response:**

ViroPharma previously produced a version of ViroPharma's 2006 organizational chart at VP\_00000001. Included in the enclosed disc, at VP\_00108941-48, is a fuller version of that organizational chart.

**SPECIFICATION 6:** Submit unredacted versions of all documents, except for purely procedural matters, produced or generated in the FDA Litigation, FOIA Litigation, Precose Litigation, and Shareholder Litigation, including but not limited to:

- A. court rulings and orders, except for purely procedural orders (such as orders granting admission pro hac vice);
- B. pleadings, motions, and all accompanying briefs, including exhibits, declarations, and other papers, except for purely procedural motions;
- C. expert reports, including any attachments or exhibits;
- D. deposition transcripts and exhibits to such transcripts;
- E. interrogatories and interrogatory responses;
- F. requests for admission, and responses to requests for admissions;
- G. documents requests and all documents produced by each party and any non-party, including all privilege logs; and
- H. documents relating to actual or potential settlement of the litigation, including but not limited to negotiations of any settlement; internal or external discussions, communications, analyses, evaluations, and notes relating to any settlement; documents relating to the projected or anticipating impact on the revenues, costs, or profitability of Vancocin; and drafts of any settlement agreement or term sheet (whether or not incorporated in the executed agreement).

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**Response:**

As you know, ViroPharma already produced materials for the FDA Litigation, FOIA Litigation, and Precose Litigation. The current production includes entries from the docket of the Shareholder Litigation. The documents are included in the enclosed disc and can be found at VP\_00108788–807. This production also includes updated filings from the FDA Litigation, available at VP\_00108949–9082.

**SPECIFICATION 13:** Identify, in ViroPharma’s acquisition from Eli Lilly & Co. of rights to Vancocin:

- A. the date ViroPharma first entered discussions with Eli Lilly & Co.;
- B. the date ViroPharma entered into agreement with Eli Lilly & Co.; and
- C. the purchase price, including any royalties.

**Response:**

- 13(A): ViroPharma first entered discussions Eli Lilly & Co. (Lilly) on or about January 2004;
- 13(B): the ViroPharma Agreement with Lilly for the acquisition of U.S. rights to Vancocin is dated Nov. 9, 2004;
- 13(C): the purchase price, as stated in the Agreement, was \$116,000,000.00. The royalty payment schedule for Vancocin is set forth in section 2.2(c) of the Agreement (pages 23-24), available at VP\_00108208–593.

**SPECIFICATION 15:** Identify ViroPharma’s reason(s) for withdrawing the oral solution form of Vancocin (NDA No. 061667) from the market.

**Response:**

As already noted, this question appears to be premised on the assumption that ViroPharma had rights to NDA No. 061667. Given that ViroPharma was not the NDA holder to No. 061667, ViroPharma did not withdraw the oral solution form of Vancocin from the market. Eli Lilly & Co. (Lilly)—the appropriate NDA holder—did. Please find enclosed publicly available documents from the FDA demonstrating that Lilly withdrew the oral form solution in June 2004, before ViroPharma acquired the rights to Vancocin in November 2004.

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**SPECIFICATION 30:** Identify all products that ViroPharma believes have competed, compete, or may compete in the United States with (1) Vancocin and (2) Generic Vancocin, and provide all documents relating to all products identified.

**Response:**

ViroPharma tracks the commercially available and investigational treatment options for patients suffering from *clostridium difficile*. Below are products that ViroPharma believes competed or may compete in the United States with Vancocin. The products are grouped into four separate categories:

- first, marketed drugs indicated to treat CDAD;
- second, marketed drugs not indicated to treat CDAD but frequently prescribed by doctors off-label to do so;
- third, non-FDA approved products; and
- fourth, pipeline products not yet approved.

This answer is based on a spreadsheet kept by ViroPharma, on a disc enclosed, and can be found at VP\_00109083.

Further documents relating to these drugs will be produced on a rolling basis as ViroPharma's documents are reviewed. Already produced IMS data relates to Generic Vancocin and Dificid and is available at VP\_00108637-797.

**Marketed Drugs**

Brand Name	Generic Name	Developer/Manufacturer
Vancocin	Oral Vancomycin Capsules	various generic manufacturers
	Vancomycin IV	various generic manufacturers
Dificid	Fidaxomicin	Optimer Pharmaceuticals
Tygacil	Tigecycline	Michigan State University with Pfizer

**Marketed Drugs (Off-Label)**

Brand Name	Generic Name	Developer/Manufacturer
Flagyl	Metronidazole	various generic manufacturers
Xifaxan	Rifaximin	Salix Pharmaceuticals
Questran	Cholestyramine Resin	Par Pharma
Alinia	Nitazoxanide	Romark Laboratories
Tindamax	Tinidaxole	Mission
Fasigyn	Tinidaxole	Pfizer
Imodium	Loperamide	various generic manufacturers

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## Pipeline Drugs

Brand Name	Generic Name	Developer/Manufacturer
	Ramoplanin	Nanotherapeutics
Exodif	Tolvamer	Genzyme
MIYA-BM	MIYA-BM Fines Granules	Osel, Inc.
BIO-K + CL-1285	Probiotics Lactobacillus acidophilus, Lactobacillus casei	BIO-K Plus International Inc.
	MK-3415, MK-6072 and MK 3415A	Merck
	EV-021	Evola Holdings, S.A.
	Non-toxigenic <i>Clostridium Difficile</i>	ViroPharma
	ILY103	Ilypsa/Cubist
	recombinant human lactoferrin	Ventria Bioscience
	oritavancin	Targanta Therapeutics Corp
	CRS3123	Crestone, Inc.
ACAM-CDIFF	Clostridium Difficile Toxoid Vaccine	Sanofi-Pasteur Holdings
VSL#3	Probiotics	National Health Service, UK, Ferring Pharmaceuticals
	CB-315	Cubist
Cadazolid	ACT-179811	Actelion (Basel)
	Unnamed product	Progenics Pharmaceuticals
	NVB302	Novaacta Biosystems
	Unnamed product	Immunome Inc.
	SMT 19969	Summit plc and Wellcome Trust
	LFF571	Novartis
	IC84	Intercell, A.G.
	ETX1153c / Clostriban	eTherapeutics
	MGB-BP-3	MGB Biopharma Ltd.
	Calcium Aluminosilicate Anti-Diarrheal	Salix Pharmaceuticals
	CSA-13	N8 Medical Inc.
	Metronidazole-DRF1 and Metronidazole-DRF2	Dr. Reddy's Laboratories Limited
	Synthetic Stool	Academia - Queen's University, Kingston, ONT, CAN
Nu-Lytely	PEG 3350	Braintree Laboratories

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**Non-FDA Regulated Products**

<b>Brand Name</b>	<b>Generic Name</b>	<b>Developer/Manufacturer</b>
	Colostrum	Hadassah Medical Organization
	Fecal transplants	Practiced by multiple clinicians
Anaeban and Inflammaban	Bacillus subtilis Straint PB6	Kemin Pharma

**SPECIFICATION 32:** Identify how the pricing for Vancocin is determined, including but not limited to any promotions, rebates, or discounts offered, and competitive responses to any product identified in response to Specification 30.

**Response:**

ViroPharma only sells Vancocin to wholesalers. ViroPharma does not have any relationship with direct customers.

In terms of rebates, promotions, and discounts, the only discount to trade that ViroPharma offers is a prompt payment discount to wholesalers of two percent (2%) net for payment within thirty days. ViroPharma also participates in several governmental discount programs, specifically the Federal Supply Schedule, Public Health Service 340B, and Medicaid. The discount provided to each program is determined according to a statutory formula. ViroPharma also participates in the Medicare Part D Coverage Gap program, but does not provide any discounts to any Part D prescription drug plan. ViroPharma does not provide other discounts, such as to PBMs or other indirect purchasers.

In determining Vancocin's pricing, ViroPharma takes various factors into account, including the value of the treatment and the pricing dynamics for the various treatments settings in which the product is used (outpatient, hospital, and long-term care). ViroPharma has not offered any rebates or discounts in response to any competitor action or launch. Upon the entry of generic vancomycin oral capsule products, ViroPharma entered into an agreement which made available an authorized generic version of Vancocin.

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**SPECIFICATION 33:** Identify the ten largest non-governmental purchasers of Vancocin, based on 2011 sales, and list their total 2011 purchases in units and in dollars.

**Response:**

ViroPharma's customers are wholesalers, as stated in response to Specification 32. Below are ViroPharma's ten largest purchasers of Vancocin based on 2011 sales.

Rank	Customer Name	Shipped Quantity	Total Sales Amount (\$)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

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**ViroPharma's General Responses and Objections**

The following General Responses and Objections and statements shall be applicable to, and shall be included in, ViroPharma's response to each Specification, whether or not mentioned expressly in any particular response. ViroPharma does not waive any of its General Objections by stating specific responses and objections to any particular Specification. In addition, ViroPharma's objections and responses are based solely on ViroPharma's current knowledge and belief. ViroPharma reserves the right to modify and supplement any of its responses and to assert additional objections as it deems necessary and/or appropriate.

1. ViroPharma objects to this civil investigative demand (CID) on the whole because all of its petitioning activity is constitutionally and statutorily protected by the First Amendment and *Noerr-Pennington* doctrine. ViroPharma has immunity from applicable antitrust laws in the context of the conduct in question.

2. ViroPharma objects to the CID and each Specification to the extent that it is overly broad, unduly burdensome and seeks documents that are neither relevant to the subject matter involved in this action nor reasonably calculated to lead to the discovery of admissible evidence. ViroPharma objects to the CID's requirement that it certify that it has produced all documents in its "knowledge" as overly broad, unduly burdensome, oppressive, impractical, and vague.

3. ViroPharma objects to each Specification as unduly burdensome given that it purports to seek information from nearly nine (9) years ago, or otherwise not limited to a time frame relevant to this investigation.

4. ViroPharma's responses are provided without prejudice to ViroPharma's right to object to the admissibility or use of any document produced by ViroPharma or any other party or

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third party. ViroPharma's production of a document in response to these Specifications should not be taken as an admission concerning its authenticity, relevance, or admissibility.

5. ViroPharma's production of documents in response to these Specifications should not and cannot be used in the context of any other matter, proceeding, or litigation. Further, any statement in these responses that ViroPharma will produce any non-privileged, responsive documents that are discovered in a reasonable search of files within its possession, custody, or control, should not be construed as an assertion that any such documents exist; such a statement means only that ViroPharma will conduct a reasonable, good-faith search for any such documents and will produce any non-privileged, responsive documents that are found.

6. ViroPharma expressly reserves its right to rely, at any time, upon subsequently discovered information or information omitted from the specific Specifications set forth below as a result of mistake, oversight or inadvertence.

7. ViroPharma objects generally to the Federal Trade Commission's (FTC) demand that production occur by September 28th as unreasonable, unduly burdensome, and oppressive because of the scope of definitions and information sought in each Specification. ViroPharma will produce responsive non-privileged documents and/or information, subject to the objections set forth herein, on a rolling basis.

8. ViroPharma objects to each Specification to the extent that it seeks the identification or disclosure of information protected by the attorney-client privilege, attorney work product immunity, common interest privilege or any other applicable privilege or immunity. ViroPharma hereby asserts such privileges and immunities to the extent that they are implicated by each Specification, and excludes privileged and protected information from its

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responses. Nothing produced by ViroPharma pursuant to any Specification constitutes a waiver of any such applicable privilege or immunity.

9. ViroPharma objects to each Specification to the extent it seeks the production of documents and things that may be subject to an obligation of confidentiality to any third-party, whether by agreement or applicable court order.

10. ViroPharma objects to each Specification to the extent that it purports to compel ViroPharma to produce a document or information not already in existence.

11. ViroPharma objects to each Specification to the extent the discovery sought is unreasonably cumulative or duplicative, or is obtainable by the FTC from some other source that is more convenient, less burdensome, or less expensive.

12. ViroPharma objects to each Specification to the extent that it seeks the production of documents and things that are publicly accessible because it is equally convenient for the FTC to obtain such documents and things. ViroPharma is not obligated to conduct literature or library searches or collect or organize information or documents and things which are as accessible to the FTC as they are to ViroPharma.

13. ViroPharma objects to each Specification to the extent it seeks the production of drafts on the grounds that such production is unduly burdensome and to the extent that it seeks production of documents that are protected by the attorney-client privilege, attorney work product immunity, any other applicable privilege or immunity and/or any agreement regarding discovery from consultants.

14. ViroPharma objects to each Specification to the extent that it seeks the production of documents and things that cannot be located after a reasonable inquiry, including an

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identification of documents that no longer exist, which is unduly burdensome and would require more than a reasonable search.

15. ViroPharma objects to providing copies of documents that may exist in the form of many multiple copies in its files. ViroPharma will produce a representative copy of such responsive, non-privileged documents.

16. ViroPharma objects to the Specifications, Instructions, and Definitions to the extent that they require the production of original documents. ViroPharma objects to the Definitions and Instructions to the extent they purport to enlarge, expand, or alter the plain meaning and scope of any Specification in a manner that results in an enlargement, expansion, or alteration that renders the Specification vague, ambiguous, unclear, overly broad, or unduly burdensome. ViroPharma will produce and/or make available for inspection copies of discoverable, responsive, non-privileged documents as appropriate.

17. The use of any definition for purposes of these Specifications shall not be deemed to constitute an agreement or acknowledgement on the part of ViroPharma that such definition is accurate, meaningful or appropriate for any other purpose in this investigation.

- a. ViroPharma objects to Definition “D” of “communication” as overly broad, burdensome, and oppressive. ViroPharma will conduct a reasonable, good-faith search for any existing documents that capture a communication and will produce any non-privileged, responsive documents.
- b. ViroPharma objects to Definition “E” of “Discuss” and “discussing” as overly broad, burdensome, and oppressive. ViroPharma will conduct a reasonable, good-faith search for any existing documents that capture a communication and will produce any non-privileged, responsive documents.

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- c. ViroPharma objects to Definition “F” of “document” as overly broad, burdensome, and oppressive. ViroPharma will conduct a reasonable, good-faith search for any existing documents that capture a communication and will produce any non-privileged, responsive documents.
- d. ViroPharma object Definition “H” and to each Specifications to the extent they seek “each,” “every,” “all,” or “any” facts, circumstances or information that relate to a particular subject. Literal interpretation of such a Specification, identifying “each,” “every,” “all,” or “any” facts, circumstances, or information, would be unduly burdensome, impractical, and oppressive and as seeking information neither relevant to the subject matter of the investigation nor reasonably calculated to lead to the discovery of admissible evidence. In such circumstances, subject to any other applicable objection, ViroPharma will make a reasonable production of responsive, non-privileged, non-immune documents relevant to a claim or defense to the extent that they exist and can be located after a reasonable search.
- e. ViroPharma objects to Definition “I” of “electronically stored information (ESI)” to the extent it calls for locating or producing ESI that is stored in historical, archival, back-up, legacy or other formats which are not reasonably accessible to ViroPharma. A search and production of such ESI would be overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. ViroPharma will search ESI in accordance with reasonable efforts, but objects to each Specification to the extent that it seeks information that would require ViroPharma to exceed reasonable efforts.

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- f. ViroPharma objects to the Definition “M” of “Identify” as overly broad, burdensome, and impractical. ViroPharma does not formally track information, including current employer, residence, or telephone number, for its former employees; nor does ViroPharma intend to include information regarding residence and telephone number for its current employees. Information relating to current employees may be obtained through counsel as appropriate.
- g. ViroPharma objects to Definition “N” of “person” as overly broad, burdensome, and impractical as this information and/or documents are not within ViroPharma’s possession, custody, or control.
- h. ViroPharma objects to Definition “O” of “Plan” as overly broad, burdensome, and vague.
- i. ViroPharma objects to Definition “Q” of “relate” and “relating to” as overly broad, burdensome, impractical, and vague. ViroPharma will conduct a reasonable, good-faith search and will product any non-privileged, responsive documents.
- j. ViroPharma objects to Definition “S” of “projected to be marketed” as vague.
- k. ViroPharma objects to Definition “X” of “ViroPharma” as overly broad, burdensome, and oppressive to the degree it includes “consultants, agents, and representatives,” as these entities may possess documents or information that are not in the possession, custody, or control of ViroPharma. ViroPharma will conduct a reasonable, good-faith search and will produce any non-privileged, responsive documents.

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18. ViroPharma objects to Instruction No. 2 to the extent it imposes obligations beyond reasonable efforts.

19. ViroPharma objects to Instruction No. 4 and to each applicable Specification to the extent that it seeks to compel ViroPharma to provide documents and things not within the possession, custody, or control of ViroPharma, including, specifically, the documents of ViroPharma's outside attorneys and agents, and/or the documents of any third parties. Any objection or lack of objection to a Specification, or any offer by ViroPharma to produce documents is not an admission by ViroPharma that it possesses documents related to the Specification or that it otherwise has possession, custody, or control of the documents.

20. ViroPharma objects to Instruction No. 5 as overly broad and unduly burdensome.

21. ViroPharma objects to Instruction No. 6(d) as unduly burdensome and 6(e) as overly broad.

22. ViroPharma objects to Instruction No. 7 as overly broad and unduly burdensome to the extent that it calls for privileged material.

23. ViroPharma objects to Instruction No. 8 as overly broad and unduly burdensome to the extent it calls for information beyond what is necessary to determine whether a communication is subject to the attorney-client privilege or other basis of non-disclosure.

24. ViroPharma objects to Instruction No. 9 as overly broad and unduly burdensome.

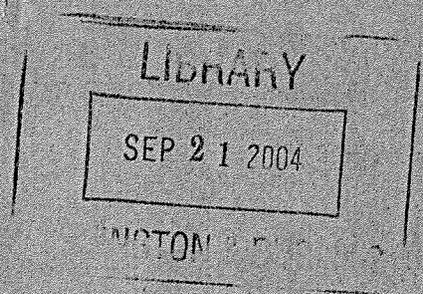
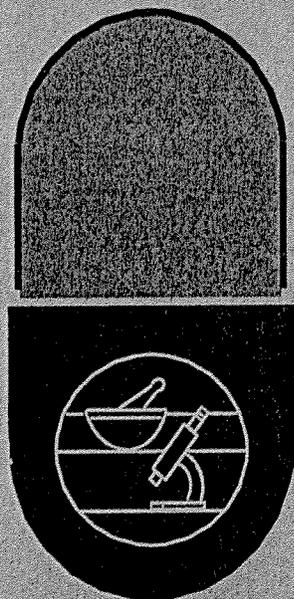
25. ViroPharma objects to Instruction No. 12 to the extent that it calls for privileged material.

26. ViroPharma objects to Instruction No. 13 as unduly burdensome.

27. ViroPharma objects to Instruction No. 14(c) as unduly burdensome and irrelevant and 14(d) as overly broad and unduly burdensome.

**CUMULATIVE  
SUPPLEMENT 6  
JUNE 2004**

FOOD DRUG  
READY REFERENCE



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**24<sup>th</sup> EDITION**

**Department of Health and Human Services**  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Generic Drugs

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DRUG  
RM  
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COVINGTON & BURLING



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2004

APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS

24<sup>th</sup> EDITION

CUMULATIVE SUPPLEMENT 6  
June 2004

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 24th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 23rd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 24th Edition. The current edition Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms, Section A, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >D> (DELETE) to the left of the line. The information line with the >D> symbol is dropped in subsequent Cumulative Supplements for that item.

## 1.2 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

### APPLICANT NAME CHANGES

FORMER APPLICANT NAME  
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

BERLEX  
(BERLEX)  
BERLEX LABORATORIES INC  
(BERLEX LABS)  
BERLEX LABORATORIES INC SUB SCHERING AG  
(BERLEX)  
AMERSHAM HEALTH  
(AMERSHAM)

BERLEX INC  
(BERLEX INC)  
BERLEX INC  
(BERLEX INC)  
BERLEX INC  
(BERLEX INC)  
GE HEALTHCARE  
(GE HEALTHCARE)

1.3 RIBAVIRIN 200MG ORAL CAPSULE

The footnote for Ribavirin 200MG capsule product 001 was inadvertently omitted from the 24<sup>th</sup> Edition. The footnote: Indicated for use and comarketed with interferon alfa-2b, recombinant (Intron A), as Rebetron Combination Therapy.

1.4 LEVOTHYROXINE SODIUM

Because there are multiple reference listed drugs of levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character TE codes may be potentially confusing and inadequate for these drug products. Accordingly, FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium drug products.

Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets.

Levo-T (Alara NDA 021342) and Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Synthroid (Abbott NDA 021402) tablets.

Levo-T (Alara NDA 021342), Unithroid (Jerome Stevens NDA 021210) and Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King/Jones Pharma NDA 021301) tablets.

Novothyrox (Genpharm NDA 021292) requires further investigation and review to establish therapeutic equivalence to corresponding strengths of any other levothyroxine sodium drug products and is rated BX.

Thyro-Tabs (Lloyd NDA 021116) requires further investigation and review to establish therapeutic equivalence to corresponding strengths of any other levothyroxine sodium drug products and is rated BX.

Levolet (Vintage NDA 021137) requires further investigation and review to establish therapeutic equivalence to corresponding strengths of any other levothyroxine sodium drug products and is rated BX.

The chart outlines TE codes for all 0.025mg products with other products being similar. Therapeutic equivalence has been established between products that have the same AB+number TE code. More than one TE code may apply to some products. One common TE code indicates therapeutic equivalence between products.

Trade Name	Applicant	Potency	TE Code	Appl No	Product No
UNITHROID	STEVENS J	0.025MG	AB1	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB1	76187	001
LEVOXYL	JONES PHARMA	0.025MG	AB1	21301	001
SYNTHROID	ABBOTT	0.025MG	AB2	21402	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB2	76187	001
LEVO-T	ALARA PHARM	0.025MG	AB2	21342	001

Trade Name	Applicant	Potency	TE Code	Appl No	Product No
LEVOXYL	JONES PHARMA	0.025MG	AB3	21301	001
LEVO-T	ALARA PHARM	0.025MG	AB3	21342	001
UNITHROID	STEVENS J	0.025MG	AB3	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB3	76187	001
NOVOTHYROX	GENPHARM	0.025MG	BX	21292	001
THYRO-TABS	LLOYD	0.025MG	BX	21116	001
LEVOLET	VINTAGE PHARMS	0.025MG	BX	21137	001

### 1.5 AVAILABILITY OF THE EDITION

The 24th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents  
Government Printing Office  
P.O. Box 371954  
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800 or toll free 866-512-1800. The cost is \$110.00 annually. A GPO Orange Book Subscription form is provided at the end of each cumulative supplement.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

The Electronic Orange Book Query (EOB) is at <http://www.fda.gov/cder/ob>. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product. The data is updated concurrently with the publication of the monthly cumulative supplements.

The Internet version of the Orange Book annual edition is at <http://www.fda.gov/cder/orange/adp.htm>.

The Internet version of the monthly supplement is at <http://www.fda.gov/cder/orange/supplement/cspreface.htm>.

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are zipped into zipobtxt.exe. The files are updated concurrently with the publication of the monthly cumulative supplements. Appendix A and Appendix B text files of the paper annual Orange Book are updated quarterly.

The 24th annual edition of the 2003 Orange Book Patent and Exclusivity List is at

<http://www.fda.gov/cder/orange/24bookpub.pdf>.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at <http://www.fda.gov/cder/orange/supplement/patents.pdf>.

The Patent Term Extension and new Patents, Docket Number \*95S-0117, is at <http://www.fda.gov/cder/orange/docket.pdf>. It is updated approximately weekly. Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from Program Support Center Forms Download Website, <http://forms/psc.gov/forms/FDA/fda.html>

The current listing of the Orphan Product Designations and Approvals is available at <http://www.fda.gov/orphan/designat/list.htm>.

## 1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

### DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 2003) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

### DEFINITIONS

#### Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

#### New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LISTCOUNTS CUMULATIVE BY QUARTER

<u>CATEGORIES COUNTED</u>	<u>DEC 2003</u>	<u>MAR 2004</u>	<u>JUN 2004</u>	<u>SEP 2004</u>
DRUG PRODUCTS LISTED	10665	10668	10702	
SINGLE SOURCE	2423 (22.7%)	2404 (22.5%)	2385 (22.3%)	
MULTISOURCE	8134 (76.3%)	8156 (76.5%)	8209 (76.7%)	
THERAPEUTICALLY EQUIVALENT	7856 (73.7%)	7885 (73.9%)	7995 (74.7%)	
NOT THERAPEUTICALLY EQUIVALENT	278 (2.6%)	271 (2.5%)	214 (2.0%)	
EXCEPTIONS <sup>1</sup>	108 (1.0%)	108 (1.0%)	108 (1.0%)	
NEW MOLECULAR ENTITIES APPROVED	6	3	1	
NUMBER OF APPLICANTS	601	586	602	

<sup>1</sup>Amino acid-containing products of varying composition (see Introduction, page xx of the List).

### 1.7 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Approval number, product number, and approval date. The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be preceded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.

- DISC Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.
- WDAG Withdrawn. The applicant holder has notified the FDA in writing that the product is no longer being marketed resulting in the product approval being withdrawn by mutual agreement. The product will be listed in the Discontinued Section.
- WDRP Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition.

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION  
TUBOCURARINE CHLORIDE

>D>	AP	+	BRISTOL MYERS SQUIBB	3MG/ML	N05657 001		Jun	CTEC
>A>				3MG/ML	N05657 001		Jun	CTEC
>D>	AP	+	HOSPIRA	3MG/ML	N06095 001		Jun	DISC
>A>		@		3MG/ML	N06095 001		Jun	DISC
	AP	+		3MG/ML	N06095 001		May	CAHN

UREA

INJECTABLE; INJECTION  
STERILE UREA

		@	HOSPIRA	40GM/VIAL	N17698 001		May	CAHN
		+	HOSPIRA	40GM/VIAL	N12154 001		May	CAHN

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL  
VALTREX

		+	GLAXOSMITHKLINE	EQ 1GM BASE	N20487 002	Jun 23, 1995	Feb	CRLD
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VANCOMYCIN HYDROCHLORIDE

>D> FOR SOLUTION; ORAL

>D>			VANCOVIN HCL					
>D>		+	LILLY	EQ 250MG BASE/5ML	N61667 002	Jul 13, 1983	Jun	DISC
>A>		@		EQ 250MG BASE/5ML	N61667 002	Jul 13, 1983	Jun	DISC
>D>		+		EQ 500MG BASE/6ML	N61667 001		Jun	DISC
>A>		@		EQ 500MG BASE/6ML	N61667 001		Jun	DISC

INJECTABLE; INJECTION

VANCOVIN HCL

>D>	AP	+	LILLY	EQ 500MG BASE/VIAL	N60180 001		Jun	DISC
>A>		@		EQ 500MG BASE/VIAL	N60180 001		Jun	DISC
>D>	AP			EQ 500MG BASE/VIAL	N62476 001	Mar 15, 1984	Jun	DISC
>A>		@		EQ 500MG BASE/VIAL	N62476 001	Mar 15, 1984	Jun	DISC
>D>	AP			EQ 500MG BASE/VIAL	N62716 001	Mar 13, 1987	Jun	DISC
>A>		@		EQ 500MG BASE/VIAL	N62716 001	Mar 13, 1987	Jun	DISC
>D>	AP			EQ 500MG BASE/VIAL	N62812 001	Nov 17, 1987	Jun	DISC
>A>		@		EQ 500MG BASE/VIAL	N62812 001	Nov 17, 1987	Jun	DISC
>D>	AP	+		EQ 1GM BASE/VIAL	N60180 002	Mar 21, 1986	Jun	DISC
>A>		@		EQ 1GM BASE/VIAL	N60180 002	Mar 21, 1986	Jun	DISC
>D>	AP			EQ 1GM BASE/VIAL	N62476 002	Mar 21, 1986	Jun	DISC
>A>		@		EQ 1GM BASE/VIAL	N62476 002	Mar 21, 1986	Jun	DISC
>D>	AP			EQ 1GM BASE/VIAL	N62716 002	Mar 13, 1987	Jun	DISC
>A>		@		EQ 1GM BASE/VIAL	N62716 002	Mar 13, 1987	Jun	DISC
>D>	AP			EQ 1GM BASE/VIAL	N62812 002	Nov 17, 1987	Jun	DISC
>A>		@		EQ 1GM BASE/VIAL	N62812 002	Nov 17, 1987	Jun	DISC
>D>	AP	+		EQ 10GM BASE/VIAL	N62812 003	Nov 17, 1987	Jun	DISC
>A>		@		EQ 10GM BASE/VIAL	N62812 003	Nov 17, 1987	Jun	DISC
			VANCOMYCIN HCL					
	AP		HOSPIRA	EQ 500MG BASE/VIAL	N62911 001	Aug 04, 1988	May	CAHN
	AP			EQ 500MG BASE/VIAL	N62931 001	Oct 29, 1992	May	CAHN
	AP			EQ 1GM BASE/VIAL	N62912 001	Aug 04, 1988	May	CAHN
	AP			EQ 1GM BASE/VIAL	N62933 001	Oct 29, 1992	May	CAHN
	AP			EQ 5GM BASE/VIAL	N63076 001	Dec 21, 1990	May	CAHN