



**AND WHEREAS**, this Final Order is entered for settlement purposes only and does not constitute any evidence against, or an admission of liability or of any issue of fact, other than jurisdictional, or law, by Defendant Perrigo Company;

## **I. Jurisdiction and Venue**

- A. This Court has jurisdiction over Perrigo and the subject matter of this action. Perrigo's activities, including the acts and practices alleged in Plaintiff's Complaint, are in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
- B. Venue is proper in this Court under Sections 5 and 13(b) of the FTC Act, 15 U.S.C. §§ 45, 53(b). Perrigo transacts and does business in the District of Columbia.
- C.

- B. "180-day Exclusivity Period" means the six month market exclusivity period provided to the First Filer of an ANDA under 21 U.S.C. § 355(j), *et seq.*
- C. "Agreement" means anything that would constitute a contract, combinati

- J. “Date of the Agreement” means the date the Agreement is executed or otherwise goes into effect.
- K. “Dosage Form” means a category of drug delivery, including, but not limited to, the following categories: (1) tablets, (2) capsules, (3) liquids administered orally, (4) liquids administered intravenously or subcutaneously, (5) nasal sprays, (6) transdermal patches, and (7) suppositories.
- L. “Enter into” means join, participate in, implement, adhere to, maintain, organize, enforce, or facilitate.
- M. “First Commercial Marketing” has the same meaning

T. “Marketing Type” means the following two categories: over-the-counter (“OTC”) and prescription (“Rx”). For purposes of this Final Order, an ANDA Drug Product is in the OTC category if its ANDA references an NDA for a

equitable relief shall be deposited to the United States Treasury as disgorgement. Perrigo shall have no right to challenge the Plaintiff's choice of remedies under Paragraph III of this Final Order. Perrigo shall have no right to contest the manner of distribution chosen by the Plaintiff.

- C. Perrigo shall not make any claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of Perrigo's bankruptcy, the funds shall not be part of the debtor's estate, nor shall the estate have any claim or interest therein.
- D. In accordance with 31 U.S.C. § 7701, Perrigo is hereby required, unless it has done so already, to furnish to the Plaintiff its taxpayer identifying number, which shall be used for collecting and reporting on any delinquent amount arising out of Perrigo's relationship with the government.
- E. Not later than 14 days after the entry of this Final Order, Perrigo shall provide to the Commission a list of all customers that have received children's liquid suspension ibuprofen from Perrigo between December 1, 1998 through May 31, 2004 ("the time period") including (1) the customer's name, (2) the name of a contact person for the customer, (3) a telephone number for the contact person, (4) the customer's mailing address, and (5) the number of units of children's liquid suspension ibuprofen delivered by Perrigo to the customer during the time period, stated separately for each bottle size. Perrigo shall submit such list, both in the form of a paper printout and in the form of a Microsoft® Excel® compatible electronic file, to the Office of the Secretary, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, and shall submit copies to the Assistant Director for Compliance, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, and to the Assistant Director for Health

Care Services and Products, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

#### **IV. Prohibited Agreements**

**IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT** Perrigo is enjoined from Entering into, or attempting to Enter into, directly or indirectly, or through any corporate or other device, any Agreement in or affecting Commerce with any other Person in which:

- A. a party to the Agreement agrees to refrain from, or to limit, for any period of time, the research, development, manufacture, marketing, distribution or sale of an ANDA Drug Product that it Controls and that is Of The Same Kind as another ANDA Drug Product Controlled by another party to the Agreement, and
- B. a party to the Agreement is the First Filer of an ANDA with respect to:
  - 1. any ANDA Drug Product that is a subject of such Agreement, or
  - 2. any ANDA Drug





**PROVIDED FURTHER THAT**, nothing in Paragraph IV shall prohibit Perrigo from Entering into any Agreement, if such Agreement is subject to the reporting obligations of Section 7A of the Clayton Act, 15 U.S.C. 18a (“HSR Act”), and Perrigo submits a complete and accurate Notification Letter (as specified in Paragraph V of this Final Order) and a Notification and Report Form pursuant to the HSR Act for such Agreement. Nothing in this Final Order shall be construed to relieve Perrigo of any obligation to comply with the requirements of the HSR Act or

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1. the docket number and caption name of this Final Order;
2. a statement that the purpose of the Notification Letter is to give the Commission notification of an Agreement as required by Paragraph V of this Final Order;
3. identification of all parties involved in the Agreement;
4. identification of all ANDA Drug Products involved in the Agreement;
5. identification of all Persons (to the extent known) who have filed an ANDA with the FDA (including the status of such application(s)) for any ANDA Drug Product Of The Same Kind as the ANDA Drug Product(s) involved in the Agreement;
6. a copy of the Agreement; and
7. identification of the court, and a copy of the docket sheet, for every legal action that involves any party to the Agreement and that relates to any ANDA Drug Product Of The Same Kind as the ANDA Drug Product(s) involved in the Agreement.

D. Within thirty (30) days of the receipt of a written request from a representative of the Commission, Perrigo shall submit to the Commission all documents which were prepared by or for any officer(s) or director(s) of Perrigo for the purpose of evaluating or analyzing any Agreement covered by Paragraph V.A. of this Final Order. Perrigo shall retain such documents for the full term of this Order.

E. The Notification Letters to be submitted pursuant to Paragraph V.A. of this Final Order and the documents to be submitted pursuant to Paragraph V.D. of this Final Order shall be submitted to the Office of the Secretary, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, and copies of such letters and documents shall be submitted to the Assistant Director for Compliance, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, and to the Assistant

Director for Health Care Services and Products, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

## **VI. Notice and Reporting Requirements**

**IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT** Perrigo shall:

- A. File a verified, written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with this Final Order: (1) within ninety (90) days from the date this Final Order is entered, (2) annually thereafter for five (5) years on the anniversary of the date this Final Order is entered, and (3) at such other times as the Commission may request by written notice.
- B. For a period of five (5) years from the date this Final Order is entered, maintain and make available to Commission staff for inspection and copying upon reasonable notice, records sufficient to describe in detail any action taken in connection with the activities covered by this Final Order.
- C. Notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of Perrigo, (2) acquisition, merger or consolidation of Perrigo, or (3) any other change in Perrigo that may affect compliance obligations arising out of this Final Order, including but not limited to assignment or the creation or dissolution of subsidiaries.
- D. Address each notice and report required by Paragraph VI

Compliance, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue,  
NW, Washington, DC 20580.

**VII. Termination of Final Order**

**IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT** this Final Order shall take effect on, and expire ten (10) years from, the date this Final Order is entered.

**VIII. Retention of Jurisdiction**

**IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT** the Court retains  
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**X. Public Interest**

**IT IS F**