

owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance

Compliance with this AD is required as indicated, unless already done.

To prevent an uncontained engine failure and damage to the airplane, resulting from cracks in the low pressure turbine rotor (LPTR) stage 2 disk, do the following:

(a) Remove from service LPTR stage 2 disks, part numbers (P/N's) 9061M22P08 and 9061M22P10 in accordance with Table 1 as follows:

TABLE 1.—LPTR STAGE 2 DISK REMOVAL SCHEDULE

If disk cycles-since-new (CSN) on the effective date of this AD are	Then remove disk
(1) Fewer than 5,300 CSN.	Before exceeding 10,400 CSN.
(2) 5,300 CSN or more, but fewer than 10,400 CSN.	Within 5,100 additional cycles-in-service from the effective date of this AD.
(3) 10,400 CSN or more.	At next LPTR stage 2 disk exposure, or by 15,500 CSN, whichever occurs earlier.

(b) After the effective date of this AD, do not install any LPTR stage 2 disk, P/N 9061M22P08 or 9061M22P10, that has 10,400 or more CSN into an engine.

(c) Except for as provided in paragraph (a) of this AD, this action establishes a new, cyclic life limit of 10,400 CSN for LPTR stage 2 disk, P/N 9061M22P08 and 9061M22P10, which is published in Chapter 05-10-00 of CF6-45 and CF6-50 Engine Shop Manual, GEK 50481.

Definition

(d) For the purpose of this AD, LPTR stage 2 disk exposure is defined as disassembly and removal of the LPTR stage 2 disk from the LPTR structure, regardless of whether any blades, bolts, nuts, bolt retainers, blade retainers, blade inserts, balance weights, wear strips, or seals remain assembled to the disk.

Alternative Methods of Compliance

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(f) Special flight permits may be issued in accordance §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be done.

Effective Date

(g) This amendment becomes effective on March 15, 2002.

Issued in Burlington, Massachusetts, on January 31, 2002.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 02-3064 Filed 2-7-02; 8:45 am]

BILLING CODE 4910-13-U

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 140

RIN 3038-AB85

Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission is revising certain provisions of its regulations on the ethical conduct of employees relating to business and financial transactions and interests. This action relates solely to the Commission's organization, procedure, and practice.

EFFECTIVE DATE: February 8, 2002.

FOR FURTHER INFORMATION CONTACT:

Susan Nathan, Assistant General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone: (202) 418-5000; e-mail: snathan@cftc.gov.

SUPPLEMENTARY INFORMATION: The Commodity Futures Trading Commission is today adopting amendments to subpart C of part 140, 17 CFR part 140, under the Commodity Exchange Act, as amended, 7 U.S.C. 4a(f) and (j), 12a(5) and 13. The amendments to § 140.735-2 remove certain restrictions on business and financial transactions by and interests held by or on behalf of a Commission member or employee where the interest was obtained prior to the

commencement of employment, or acquired by inheritance, gift, merger, acquisition or other change in corporate ownership, or acquired by a spouse or minor child as part of an employee compensation package. In addition, the rule would retain the 10 percent limitation on an employee's financial interest in any person required to file reports under the Commodity Exchange Act or rules and regulations promulgated thereunder, but would eliminate from the definition of "significant ownership" the \$25,000 total investment in the entity. The amendments do not eliminate the current reporting and disqualification requirements prescribed by the Part 140 rules or by the Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR part 2635; OGE Standard Forms 278 and 450; the restrictions in sections 2(a)(7) and 9 of the CEA; and the statutory prohibition against participating in matters affecting an employee's own financial interests, 18 U.S.C. 208.

The amendments to § 140.735-8(b)(3) clarify the duties of the General Counsel as ethics counsel as well as the process by which actual or apparent conflicts of interests are to be resolved.

The Commission has determined that the exceptions to the prohibitions against financial interests created by these amendments are neither contrary to the public interest nor otherwise inconsistent with the purposes of section 9(c) of the CEA, which generally makes it a felony for a Commissioner or Commission employee to participate, directly or indirectly, in commodity futures, option or leverage transactions or, with certain limited exceptions, in investment transactions in actual commodities.¹

The Commission has determined that this rule relates solely to agency organization, procedure and practice. Accordingly, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, which generally require notice of proposed rulemaking and opportunity for public participation, are not applicable. The Commission further finds that there is good cause to make

¹ The Futures Trading Act of 1986 amended section 9(c) to replace specific exceptions to that section's prohibitions with a grant of authority to the Commission to develop, by rule, appropriate exceptions to the absolute restrictions against participation in futures and options transactions where the Commission determines that such investments would pose no conflict of interest concerns. This amendment was designed to enable the Commission to administer section 9(c) flexibly and to obviate the need for further amendments to 9(c) as the commodities markets continue to expand into new areas. H.R. Rep. No. 99-624, 99th Cong., 2d Session., at 11-12 (June 6, 1986).

this rule effective upon publication in the **Federal Register**.

Related Matters

Cost-Benefit Analysis

Section 15 of the CEA requires the Commission to consider the costs and benefits of its action before issuing a new regulation under the Act. The Commission understands that, by its terms, section 15 does not require the Commission to quantify the costs and benefits of a new regulation or to determine whether the benefits of the regulation outweigh its costs. Section 15 specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: Protection of market participants and the public; efficiency, competitiveness and financial integrity of futures markets; price discovery; sound risk management practices; and other public interest considerations. Accordingly, the Commission could in its discretion give greater weight to any one of the five enumerated areas of concern and could in its discretion determine that, notwithstanding its costs, a particular rule was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the Act.

Because the amendments to part 140 relate solely to agency organization, procedure and practice, they do not directly implicate the specific areas of concern identified in section 15. The Commission has considered the costs and benefits of these amendments and has concluded that the rules are fully consistent with the public interest and with the requirements and prohibitions of the Commodity Exchange Act, as amended, 7 U.S.C. 4a(f) and (j), 12a(5), and 13.

Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*, imposes certain requirements on federal agencies in connection with conducting or sponsoring any collection of information as defined in the PRA. The Commission has determined that this rulemaking does not impose any information collection requirements as defined by the PRA.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires that federal agencies, in rules, consider the impact of those rules on small entities. The Commission has determined that the provisions of the RFA do not apply to the promulgation of these regulations

since they relate solely to agency procedure and practice.

List of Subjects in 17 CFR Part 140

Conflict of interests, Ethics, Organization and functions.

Text of Final Rule

For the reasons set forth in the preamble, the Commission amends Title 17, part 140, of the Code of Federal Regulations as follows:

PART 140—[AMENDED]

Subpart C—Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission

1. The authority citation for part 140, subpart C, is revised to read as follows:

Authority: 7 U.S.C. 4a(f) and (j), 12a(5), and 13, as amended by the Commodity Futures Modernization Act of 2000, Appendix E of Pub. L. 106-554, 114 Stat. 2763 (2000).

2. Section 140.735-1 is revised to read as follows:

§ 140.735-1 Authority and purpose.

This subpart sets forth specific standards of conduct required of Commission members, employees of the Commission, and special government employees as well as regulations concerning former Commissioners, employees, and special government employees of the Commodity Futures Trading Commission. These rules are separate from and in addition to the Office of Government Ethics' conduct rules, Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR part 2635. In addition, this subpart contains references to various statutes governing employee conduct in order to aid Commission members, employees of the Commission and others in their understanding of statutory restrictions and requirements.¹ Absent compelling countervailing reasons, all Commission members and employees are subject to all the terms of this section.

3. Section 140.735-2 is revised to read as follows:

§ 140.735-2 Prohibited transactions.

(a) **Application.** This section applies to all transactions effected by or on behalf of a Commission member or employee of the Commission, including

¹ These references, however, do not purport to cover all restrictions and requirements, and paraphrased restatements of statutory provisions are not intended to be, and should not be construed as, verbatim quotations of the law. Statutory text should be consulted in any situation in which it might apply.

transactions for the account of other persons effected by the member or employee, directly or indirectly under a power of attorney or otherwise. A member or employee shall be deemed to have a sufficient interest in the transactions of his or her spouse, minor child, or other relative who is a resident of the immediate household of the member or employee so that such transactions must be reported and are subject to all the terms of this section.

(b) **Prohibitions.** Except as otherwise provided in this subsection, no member or employee of the Commission shall:

(1) Participate, directly or indirectly, in any transaction:

(i) In commodity futures;
(ii) Involving any commodity that is of the character of or which is commonly known to the trade as an option, privilege, indemnity, bid, offer, put, call, advance guaranty, or decline guaranty; or

(iii) For the delivery of any commodity under a standardized contract commonly known to the trade as a margin account, margin contract, leverage account, or leverage contract, or under any contract, account, arrangement, scheme, or device that the Commission determines serves the same function or functions as such a standardized contract, or is marketed or managed in substantially the same manner as such a standardized contract;

(2) Effect any purchase or sale of an option, futures contract, or option on a futures contract involving a security or group of securities;

(3) Sell a security which he or she does not own or consummate a sale by the delivery of a security borrowed by or for his or her account;

(4) Participate, directly or indirectly, in any investment transaction in an actual commodity if:

(i) Nonpublic information is used in the investment transaction;

(ii) It is prohibited by rule or regulation of the Commission; or

(iii) It is effected by means of any instrument regulated by the Commission and is not otherwise permitted by an exception under this section;

(5) Purchase or sell any securities of a company which, to his or her knowledge, is involved in any:

(i) Pending investigation by the Commission;

(ii) Proceeding before the Commission or to which the Commission is a party;

(iii) Other matter under consideration by the Commission that could have a direct and predictable effect upon the company; or

(6) Recommend or suggest to another person any transaction in which the

member or employee is not permitted to participate in any circumstance where the member or employee could reasonably expect to benefit or where the member or employee has or may have control or substantial influence over such person.

(c) *Exception for farming, ranching, and natural resource operations.* The prohibitions in paragraphs (b)(1)(i) and (ii) of this section shall not apply to a transaction in connection with any farming, ranching, oil and gas, mineral rights, or other natural resource operation in which the member or employee has a financial interest, if he or she is not involved in the decision to engage in, and does not have prior knowledge of, the actual futures or options transaction and has previously notified the General Counsel² in writing of the nature of the operation, the extent of the member's or employee's interest, the types of transactions in which the operation may engage, and the identity of the person or persons who will make trading decisions for the operation;³

(d) *Other exceptions.* The prohibitions in paragraphs (b)(1), (2) and (3) of this section shall not apply to:

(1) A transaction entered into by any publicly-available pooled investment vehicle (such as a mutual fund or exchange-traded fund) other than one operated by a person who is a commodity pool operator with respect to such entity if the direct or indirect ownership interest of the member or employee neither exercises control nor has the ability to exercise control over the transactions entered into by such vehicle;⁴

² As used in this subpart, "General Counsel" refers to the General Counsel in his or her capacity as counselor for the Commission and designated agency ethics official for the Commission, and includes his or her designee and the alternate designated agency ethics official appointed by the agency head pursuant to 5 CFR 2638.202.

³ Although not required, if they choose to do so, members or employees may use powers of attorney or other arrangements in order to meet the notice requirements of, and to assure that they have no control or knowledge of, futures or options transactions permitted under paragraph (c) of this section. A member or employee considering such arrangements should consult with the Office of General Counsel in advance for approval. Should a member or employee gain knowledge of an actual futures or option transaction entered into by an operation described in paragraph (c) of this section that has already taken place and the market position represented by that transaction remains open, he or she should promptly report that fact and all other details to the General Counsel and seek advice as to what action, including recusal from any particular matter that will have a direct and predictable effect on the financial interest in question, may be appropriate.

⁴ Section 9(c) of the Commodity Exchange Act makes it a felony for any member or employee, or agent thereof, to participate, directly or indirectly in, *inter alia*, any transaction in commodity futures, option, leverage transaction, or other arrangement

(2) The acceptance or exercise of any stock option or similar right granted by an employer as part of a compensation package to a spouse or minor child or other related member of the immediate household of a member or employee, or to the exercise of any stock option or similar right granted to the member or employee by a previous employer prior to commencement of the member's or employee's tenure with the Commission as part of such member's or employee's compensation package from such previous employer;

(3) A transaction by any trust or estate of which the member or employee or the spouse, minor child, or other related member of the immediate household of the member or employee is solely a beneficiary, has no power to control, and does not in fact control or advise with respect to the investments of the trust or estate;

(4) The exercise of any privilege to convert or exchange securities, of rights accruing unconditionally by virtue of ownership of other securities (as distinguished from a contingent right to acquire securities not subscribed for by others), or of rights in order to round out fractional shares in securities;

(5) The acceptance of stock dividends on securities already owned, the reinvestment of cash dividends on a security already owned, or the participation in a periodic investment plan when the original purchase was otherwise consistent with this rule; or

(6) Investment in any fund established pursuant to the Federal Employees Retirement System.

(e) *No prohibition on stocks or funds.* Nothing in paragraph (b)(1) or (2) of this section shall prohibit a member or employee from purchasing, selling, or retaining any share that represents ownership of a publicly-owned corporation or interest in a publicly-available pooled investment vehicle containing any such shares (such as a mutual fund or exchange-traded fund) other than one operated by a person who is a commodity pool operator with respect to such pooled investment vehicle, regardless of whether any security futures product may at any time be or have been based upon shares of such corporation or pooled investment vehicle, and regardless of whether such pooled investment vehicle may, by design or effect, track or follow any

that the Commission determines serves the same function, unless authorized to do so by Commission rule or regulation. 17 CFR 4.5 excludes certain otherwise regulated persons from the definition of "commodity pool operator" with respect to operation of specific investment entities enumerated in the regulation.

group of securities that also underlies a futures contract.

(f) *Exception applicable to legally separated employees.* This section shall not apply to transactions of a legally separated spouse of a member or employee, including transactions for the benefit of a minor child, if the member or employee has no power to control, and does not, in fact, advise or control with respect to such transactions. If the member or employee has actual or constructive knowledge of such transactions of a legally separated spouse or for the benefit of a minor child, the disqualification provisions of § 140.735-2a(d)(2)(i)-(iii) and 18 U.S.C. 208 are applicable.

4. Section 140.735-2a is added to subpart C to read as follows:

§ 140.735-2a Prohibited interests.

(a) *Application.* This section applies to all financial interests of a Commission member or employee of the Commission, including financial interests held by the member or employee for the account of other persons. A member or employee shall be deemed to have a sufficient interest in the financial interests of his or her spouse, minor child, or other relative who is a resident of the immediate household of the member or employee, so that such financial interests must be reported and are subject to all the terms of this section.

(b) *Prohibitions.* Except as otherwise provided in this subsection, no member or employee of the Commission shall:

(1) Have a financial interest, through ownership of securities or otherwise, in any person⁵ registered with the Commission (including futures commission merchants, associated persons and agents of futures commission merchants, floor brokers, commodity trading advisors and commodity pool operators, and any other persons required to be registered in a fashion similar to any of the above under the Commodity Exchange Act or pursuant to any rule or regulation promulgated by the Commission), or any contract market, board of trade, or other trading facility, or any clearing organization subject to regulation or oversight by the Commission;⁶ or

(2) Own or control, through securities or otherwise, ten percent or more of the total ownership interests in any other person required to file reports under the Commodity Exchange Act, or pursuant

⁵ As defined in section 1a(16) of the Commodity Exchange Act and 17 CFR 1.3(u) thereunder, a "person" includes an individual, association, partnership, corporation and a trust.

⁶ Attention is directed to 18 U.S.C. 208.

to any rule or regulation promulgated by the Commission.⁷

(c) *Exceptions.* The prohibitions in paragraph (b) of this section shall not apply to:

(1) A financial interest in any publicly-available pooled investment vehicle (such as a mutual fund or exchange-traded fund) other than one operated by a person who is a commodity pool operator with respect to such entity if such vehicle does not have invested, or indicate in its prospectus the intent to invest, ten percent or more of its assets in securities of persons described in paragraph (b) of this section and the member or employee neither exercises control nor has the ability to exercise control over the financial interests held in such vehicle;

(2) A financial interest in any corporate parent or affiliate of a person described in paragraph (b)(1) of this section if the operations of such person provide less than ten percent of the gross revenues of the corporate parent or affiliate;⁸

(3) A financial interest in any trust or estate of which the member or employee is solely a beneficiary, has no power to control, and does not in fact control or advise with respect to the investments of the trust or estate; except that such interest is subject to the provisions of paragraphs (d) and (f) of this section.

(d) *Retention or passive acquisition of prohibited financial interests.* Nothing in this section shall prohibit a member or employee, or a spouse or minor child or other related member of the immediate household of the member or employee, from:

(1) Retaining a financial interest that was permitted to be retained by the member or employee prior to the adoption of this regulation, was obtained prior to the commencement of employment with the Commission, or was acquired by a spouse prior to marriage to the member or employee; or

⁷ The Division of Economic Analysis maintains information on persons whose commodity futures and options positions are or have been reportable under the Commission's large trader reporting system. Members and employees should consult with DEA to determine whether any of their financial interests involve entities subject to such reporting.

⁸ It is the member's or employee's responsibility to monitor his or her financial interests and those of a spouse or minor child or other related member of his or her immediate household, to promptly report relevant changes to the General Counsel in writing, and to seek the advice of the General Counsel as to what action may be appropriate. In this regard, attention is directed to 18 U.S.C. 208, which bars an employee from participating in any particular matter that will have a direct and predictable effect on the financial interest in question.

(2) Acquiring, retaining, or controlling an otherwise prohibited financial interest, including but not limited to any security or option on a security (but not a security futures product), where the financial interest was acquired by inheritance, gift, stock split, involuntary stock dividend, merger, acquisition, or other change in corporate ownership, exercise of preemptive right, or otherwise without specific intent to acquire the financial interest, or by a spouse or minor child or other related member of the immediate household of the member or employee as part of an employment compensation package; *provided, however,* that retention of any interest allowed by paragraph (c)(3) or (d) of this section is permitted only where the employee:

(i) Makes full disclosure of any such interest on his or her annual financial disclosure (Standard Form 278 or Standard Form 450);

(ii) Makes full written disclosure to the General Counsel within 30 days of commencing employment or, for incumbents, within twenty days of his or her receipt of actual or constructive notice that the interest has been acquired;⁹ and

(iii) Will be disqualified in accordance with 5 CFR part 2635, subpart D, and 18 U.S.C. 208 from participating in any particular matter that will have a direct and predictable effect on the financial interest in question. Any Commission member or employee affected by this section may, pursuant to 18 U.S.C. 208(b)(1) and 5 CFR 2640.301–303, request a waiver of the disqualification requirement.

Note: With respect to any financial interest retained under paragraph (c)(3) or (d) of this section, Commission members and employees are reminded of their obligations under 18 U.S.C. 208 and 5 CFR part 2635, subpart D, to disqualify themselves from participating in any particular matter in which they, their spouses or minor children have a financial interest.

(e) *Exception applicable to legally separated employees.* This section shall not apply to the financial interests of a legally separated spouse of a Commission member or employee, including transactions for the benefit of

⁹ Changes in holdings, other than by purchase, which do not affect disqualification, such as those resulting from the automatic reinvestment of dividends, stock splits, stock dividends or reclassifications, may be reported on the annual statement, SF 278 or SF 450, rather than when notification of the transaction is received. Acquisition by, for example, gifts, inheritance, or spinoffs, which may result in additional disqualifications pursuant to paragraph (d)(2)(iii) of this section and 18 U.S.C. 208 shall be reported to the General Counsel within 20 days of the receipt of actual or constructive notice thereof.

a minor child, if the member or employee has no power to control and does not, in fact, advise or control with respect to such transactions. If the member or employee has actual or constructive knowledge of such financial interests held by a legally separated spouse or for the benefit of a minor child, the disqualification provisions of paragraphs (d)(2)(i)–(iii) of this section and 18 U.S.C. 208 are applicable.

(f) *Divestiture.* Based upon a determination of substantial conflict under 5 CFR 2635.403(b) and 18 U.S.C. 208, the Commission, or its designee, may require in writing that a member or employee, or the spouse or minor child or other related member of the immediate household of a member or employee, divest a financial interest that he or she is otherwise authorized to retain under this section.¹⁰

5. Section 140.735–8 is amended by republishing the introductory text of paragraph (b) and by revising paragraph (b)(3) to read as follows:

§ 140.735–8 Interpretative and advisory service.

* * * * *

(b) *Duties of the Counselor.* The counselor shall:

(3) Receive information on, and resolve or forward to the Commission for consideration, any conflict of interests or apparent conflict of interests which appears in the annual financial disclosure (Standard Form 278 or Standard Form 450), or is disclosed to the General Counsel by a member or employee pursuant to § 140.735–2a(d) of this part, or otherwise is made known to the General Counsel.

(i) A conflict of interests or apparent conflict of interests is considered resolved by the General Counsel when the affected member or employee has executed an ethics agreement pursuant to 5 CFR 2634.801 *et seq.* to undertake specific actions in order to resolve the actual or apparent conflict.

(ii) If, after advice and guidance from the General Counsel, a member or employee does not execute an ethics agreement, the conflict of interests is considered unresolved and must be referred to the Commission for resolution or further action consistent with 18 U.S.C. 208 and 28 U.S.C. 535.

(iii) *Where an unresolved conflict of interests or apparent conflict of interests is to be forwarded to the Commission by*

¹⁰ Any evidence of a violation of 18 U.S.C. 208 must be reported by the General Counsel to the Commission, which may refer the matter to the Criminal Division of the Department of Justice and the United States Attorney in whose venue the violations lie. See 28 U.S.C. 535.

the General Counsel, the General Counsel will promptly notify the affected member or employee in writing of his or her intent to forward the matter to the Commission. Any member or employee so affected will be afforded an opportunity to be heard by the Commission through written submission.

* * * * *

By the Commission on February 1, 2002.

Jean A. Webb,

Secretary.

[FR Doc. 02-2935 Filed 2-7-02; 8:45 am]

BILLING CODE 6351-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 99N-4063]

RIN 0910-AA01

Topical Antifungal Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the final monograph for over-the-counter (OTC) topical antifungal drug products to add the ingredient clotrimazole as generally recognized as safe and effective for the treatment of athlete's foot, jock itch, and ringworm. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: This rule is effective March 11, 2002.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 1993 (58 FR 49890), FDA published a final monograph for OTC topical antifungal drug products in part 333 (21 CFR part 333), subpart C. That monograph includes six antifungal active ingredients used for the treatment of athlete's foot, jock itch, and ringworm and one ingredient used for the prevention of athlete's foot. The monograph provides that two

ingredients may contain professional labeling (may be provided to health professionals but not to the general public) for the treatment of superficial infections caused by yeast (*Candida albicans*).

In the **Federal Register** of May 29, 2001 (66 FR 29059), FDA proposed to amend the final monograph to add the antifungal ingredient clotrimazole at a 1-percent concentration as generally recognized as safe and effective for the treatment of athlete's foot, jock itch, and ringworm. The agency discussed safety and effectiveness data for clotrimazole for these uses and noted it has been marketed OTC in the United States since 1989 under new drug applications (NDAs) in cream, lotion, and solution dosage forms, with a significant amount marketed in the United States and other countries since 1990.

In response to the proposal, the agency received one comment, which is on public display in the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The comment supported the agency's determination that clotrimazole has been marketed to a material extent and for a material time as a topical antifungal drug and that, based on the available data, it can be generally recognized as safe and effective for the treatment of athlete's foot, jock itch, and ringworm and included in the OTC drug monograph for this class of products.

II. The Agency's Final Conclusions

The agency has determined that clotrimazole in a 1-percent concentration has been marketed to a material extent and for a material time as a topical antifungal drug. Based on the available data, it can be generally recognized as safe and effective for the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis) and included in the OTC drug monograph for this class of products. Therefore, the agency is adding clotrimazole 1-percent as new paragraph (g) in § 333.210. Any product containing clotrimazole that is marketed under the monograph must use all of the labeling that is required by the final monograph (part 333, subpart C) and must follow the content and format requirements in 21 CFR 201.66.

This final rule does not apply to clotrimazole marketed OTC as an antifungal agent in intravaginal drug products labeled for the treatment of vaginal yeast infections. The existing monograph for topical antifungal drug products does not contain any claims for intravaginal use.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities.

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

The agency concludes that this final rule is consistent with the principles set out in the Executive order and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. Further, since this final rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation, FDA need not prepare additional analyses under the Unfunded Mandates Reform Act.

The purpose of this final rule is to include clotrimazole 1-percent in the monograph for OTC topical antifungal drug products. This rule allows current manufacturers of these products to market their products under the OTC drug monograph instead of an NDA and enables other manufacturers who wish to market clotrimazole products OTC to enter the marketplace without having to obtain an NDA. In both cases, there will be cost savings from marketing without an NDA.

When current manufacturers market these products under the OTC drug monograph, they should incur only minor costs to relabel their products to meet the monograph. Some manufacturers may have to add a warning that was included in the final monograph, but not required when