

## CITIZENS PETITION

**To: Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Drive  
Rockville, Maryland 20857**

**From: Francis W. Busch  
Executive Vice President  
Research & Development  
ProStrong Inc.  
20 Main Street  
Oakville, CT 06779**

The Food and Drug Administration issued regulations located in the Code of Federal Regulations Title 21, Volume 5, and Parts 300 to 499.

Part 333 of these regulations is Titled "Topical Antimicrobial Drug Products for Human Over the Counter Use".

Subpart C relates to Topical Antifungal Drug Products. Copies attached

Sec. 333.203 (c) defines dermatophyte as a fungus that invades and lives upon the skin or in the hair or nails.

Sec. 333.210 (e) identifies Tolnaftate 1% as an effective Topical Antifungal Drug Product.

Sec. 333.250 (2) identifies approved labeling for products containing the ingredient identified in Sec.333.210 (e) [1% tolnaftate] for the prevention of athletes foot.

These regulations were adapted after extensive study by a panel of experts and input from interested members of the public.

The proceedings of the "agency panel" along with comments from interested members of the public were recorded and made available to the public in the *FEDERAL REGISTER*. Proceedings relevant to this petition were published in the *FEDERAL REGISTER* Vol. 54, No. 237/ Tuesday, December 12<sup>th</sup> 1989 p. 51145-51146 copies attached.

2004P-0490

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## ACTION REQUESTED

A. This petition requests the Commissioner to amend the subject regulation as follows:

### The Current Regulation

Sec.333.250 (2) for products containing the ingredient identified in Sec.333.210 (e) labeled for the prevention of athlete's foot, (i) (Select one of the following: "Clinically proven to prevent," "Prevents," "Proven effective in the prevention of," "Helps prevent", "For the prevention of," "Guards against", or "Prevents the recurrence of") (select one of the following: "Athlete's foot," "athlete's foot (dermatophytes), "athlete's foot (tinea pedis), "tinea pedis" (athlete's foot) , with daily use.

### The Regulation we Propose:

Sec.333.250 (2) for products containing the ingredient identified in Sec.333.210 (e) labeled for the prevention of athlete's foot, the prevention of fungal infections of the nail or the prevention of dermatophytes of the nail. (i) (Select one of the following: "Clinically proven to prevent," "Prevents," "Proven effective in the prevention of," "Helps prevent", "For the prevention of," "Guards against", or "Prevents the recurrence of") (select one of the following: "Athlete's foot," "athlete's foot (dermatophytes), "athlete's foot (tinea pedis), "tinea pedis" (athlete's foot) , "fungal infections of the nail" or (dermatophytes of the nail" with daily use.

## STATEMENT OF GROUNDS

B. Sec.333.250 (2) recognizes the effectiveness of 1% Tolnaftate (ingredient identified in Sec.333.210 (e)) as an ingredient for the prevention of athlete's foot type fungal infections.

This regulation was issued after careful study which included a review of clinical trials demonstrating effectiveness of 1% tolinaftate in the prevention of fungal infections. Also carefully reviewed, were issues related to the safety of this ingredient. See Federal Register Vol. 54, No. 237 / Tuesday, December 12, 1989, attached. Also reported in the Federal Register Vol. 54, No. 237 / Tuesday, December 12, 1989 were comments and discussion related to a request that 1% tolinaftate be allowed for the prevention of "ring worm" and "jock itch" type fungal infections in addition to the prevention labeling for athlete's foot type infections.. The request to include the prevention of "jock itch and ring worm" was based on the same studies cited for prevention of athlete's foot infections.

The expert review panel and the FDA commissioner rejected the prevention labeling for "ring worm" and "jock itch" labeling but continued to support the prevention labeling for the athlete's foot infections.

The reason for rejecting the labeling which would have allowed 1% tolnaftate as a prevention of "ring worm" and "jock itch" was stated in the Federal Register Vol. 54, No. 237 / Tuesday, December 12, 1989, p. 51145-51146 as follows:

Italics added

Although the safety of tolnaftate in treatment of athlete's foot, jock itch, and ring worm is well established, the agency agrees with the Panel's recommendation that claims of prevention for this ingredient be limited to athletes foot. The panel concluded that tolnaftate may be used in the prevention of athletes foot, but not in the prevention of jock itch or ringworm (47 FR 12480 at 12506). The Panel recognized that use of this ingredient for prevention of these fungal conditions would likely result in long term use, whereas OTC treatment of a particular condition is limited to a specific time period. Because there is generally no limitation to the period of use when a product is used to prevent a condition, and *because the groin is a more sensitive area than the feet*, the Panel concluded that antifungal drugs including tolnaftate, should not be used indefinitely in the groin. (FR 12508)

We are petitioning the commissioner to allow labeling of 1% tolnaftate for the prevention of fungal type infections of the nail based on its recognized safety and effectiveness in the prevention of fungal infections of the feet.

Since the keratin cells that make up the external layers of the nail are inert, the chance for irritation is limited to skin immediately surrounding the nail which might inadvertently come in contact with the drug during application of product to the nail.

The panels concern about the sensitive skin in the groin area simply does not apply for products applied to the nail.

Prevention of fungal infections in the nail is a major consumer concern because once infected treatment is extremely difficult and limited to prescription drugs.

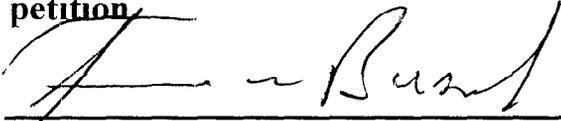
Since 1% tolnaftate is recognized as a safe and effective in the prevention of fungal infections of the feet, its use should be permitted in the prevention of fungal infections of the nail.

## ENVIRONMENTAL IMPACT STATEMENT

The labeling changes requested by this petition would not have an environmental impact different from current approved usage.

**CERTIFICATION**

**The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.**



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**Signature**

**Francis W. Busch**

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**Name of the Petitioner**

**Prostrong Inc**

**20 Main Street**

**Oakville, CT 06779**

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**Mailing Address**

**860 945 9469**

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**Phone**

**Respectively Submitted,**

**27 October 2004**

placed thymol at concentrations greater than 0.2 percent in Category II because the only clinical trial in which thymol was evaluated showed it to be ineffective in clearing athlete's foot and often irritating (47 FR 12523).

The agency has reviewed and agrees with the Panel's conclusions on thymol. The agency concludes that there are insufficient data to determine the safety of thymol at concentrations greater than 0.2 percent. The Panel determined and the agency concurs that additional data are needed to ensure the safety of thymol at concentrations greater than 0.2 percent. Based on the information it reviewed, the Panel concluded that more data are necessary on the absorption of thymol from small areas of application to broken and intact skin, on the local effects of thymol on wound healing, and on the irritation potential of thymol (47 FR 12522). However at concentrations less than or equal to 0.2 percent, thymol is safe and may be used as an inactive ingredient in formulations for product identification. The agency concurs with this recommendation.

The agency also notes that the Topical Analgesic Panel only reviewed thymol for use as an OTC external analgesic. That Panel referred thymol "to another Panel for the determination of its safety and efficacy as an antimicrobial and antifungal agent" (44 FR 69768 at 69855). Because of the different nature of the skin conditions being treated, the agency does not believe that the Topical Analgesic Panel's conclusions are applicable to the antifungal use of thymol.

Because no new data have been submitted on the effectiveness of thymol, the agency is classifying this ingredient in Category III (safety) and Category II (effectiveness) in this proposed rule.

#### L. Comments on Tolnaftate

18. Two comments stated that tolnaftate should be permitted to be labeled for the prevention of jock itch in addition to the prevention of athlete's foot. The comments noted that the Panel's reservation about long-term use of any antifungal agent in the groin (47 FR 12480 at 12490) was applied generally to all ingredients without regard to the safety margin of any ingredients. One comment added that the wide margin of safety of tolnaftate, including a very low potential for irritation, has been well established both through laboratory and clinical studies and through extensive use experience. The comment stated that results of this experience were presented to the Panel in oral and written submissions and by cross-reference to data contained in the new

drug application for tolnaftate. The other comment asserted that after 19 years of extensive controlled and uncontrolled human studies, as well as lifetime studies in animals, tolnaftate is completely nontoxic to man and animal, and the potential for systemic absorption of tolnaftate through sensitive genital tissues and the groin with resultant toxicity is a nonexistent risk.

Although the safety of tolnaftate in the treatment of athlete's foot, jock itch, and ringworm is well established, the agency agrees with the Panel's recommendation that claims of prevention for this ingredient be limited to athlete's foot. The Panel concluded that tolnaftate may be used in the prevention of athlete's foot, but not in the prevention of jock itch or ringworm (47 FR 12480 at 12508). The Panel recognized that use of this ingredient for prevention of these fungal conditions would likely result in long-term use, whereas OTC treatment of a particular condition is limited to a specific time period. Because there is generally no limitation to the period of use when a product is used to prevent a condition, and because the groin is a more sensitive area than the feet, the Panel concluded that antifungal drugs, including tolnaftate, should not be used indefinitely in the groin (47 FR 12508). The comments did not submit any new data, but referred to studies that had been reviewed by the Panel. Those studies focused on the prevention of athlete's foot and not on jock itch. Therefore, the agency concludes that clinical studies on the prevention of jock itch are needed to establish the long-term safety of using tolnaftate or any other antifungal drug in the groin area. At this time, the agency finds insufficient data to support labeling tolnaftate for the prevention of jock itch. Although the comments did not discuss the prevention of ringworm, the agency considers it appropriate to express agreement with the Panel's statement that it would be impractical to use an antifungal agent prophylactically over large areas of the body to prevent ringworm (47 FR 12490 and 12508).

19. One comment contended that the Panel's Category I recommendation for a prophylaxis claim for tolnaftate was inconsistent with the Panel's own specific requirement of a study lasting a minimum of 12 weeks (47 FR 12480 at 12563). The comment argued that in one of the studies reviewed by the Panel three of the four centers participating in the study treated their patients for only 8 weeks (Ref. 1). The fourth center, which did test for 12 weeks, failed to show any difference between vehicle

and tolnaftate therapy. The comment argued that two other studies reviewed by the Panel were also only conducted for 8 weeks (Refs. 2 and 3). The comment requested that the agency abandon the distinction between treatment and prophylaxis for antifungals because if an agent is effective in the treatment of a fungal infection it will also be effective in the prevention of the disease. As an alternate suggestion, the comment requested that the prophylaxis indication for tolnaftate be dropped. The comment also contended that the wording of § 333.250(b)(2) unfairly singles out tolnaftate. The comment requested that the heading for § 333.250(b)(2) should be in the same general format as § 333.250(b)(1), i.e., the word "tolnaftate" should not be in the heading for § 333.250(b)(2).

A reply comment stated that the referenced studies do, in fact, meet the criteria established by the Panel for prophylaxis and that the Panel properly applied these criteria in evaluating the clinical data on tolnaftate. The reply comment submitted a copy of an oral presentation made to the Panel which explains the results of the studies (Ref. 4).

The agency has reevaluated the data reviewed by the Panel to support its Category I recommendation for a prophylaxis claim for tolnaftate. The study by Charney et al. (Ref. 1) was conducted at four centers (California, Mississippi, Puerto Rico, and Texas), with a total of 168 subjects who entered the study with no evidence of fungal infection. At three of the four centers (California, Mississippi, and Puerto Rico), therapy was continued for 12 weeks with evaluations either taking place at 4, 8, and 12 weeks (Mississippi) or during the last 4 weeks of the 12-week period (California and Puerto Rico). At the other center (Texas), therapy was given for about 8 weeks. Thus, at three of the four centers the study met the Panel's 12-week criteria for length of the trial because therapy continued during the evaluation period.

The study showed that subjects treated with tolnaftate were significantly more likely to be free of athlete's foot at the end of the treatment period than were the control subjects. When the subjects at the center that continued therapy for only 8 weeks are excluded from the analysis, the following results are obtained: 36 of 41 subjects treated with tolnaftate were negative (88 percent) while 46 of 63 subjects treated with placebo were negative (73 percent). Regarding the comment's concern about the

significance of the results from one of the centers, the agency concludes that results with a p-value of less than 0.05 were obtained by pooling data from the three centers with 12-week trials.

In the study by Burrill and Nemlick (Ref. 2), therapy also continued for 12 weeks. The therapy consisted of an 8-week treatment period for each subject and a 4-week evaluation period, during which therapy continued. The study concluded that tolnaftate powder was superior to placebo in preventing the occurrence of athlete's foot in subjects free of tinea pedis at the start of the study. The study by Smith, Dickson, and Knox (Ref. 3) was similar in design to the Burrill and Nemlick study and arrived at a similar conclusion; however, the report of the Smith study did not make clear whether therapy continued during the evaluation period or only during the 8-week treatment period.

Although one part of the Charney study does not meet the Panel's 12-week criteria, the remainder of the Charney study and the Burrill and Nemlick study do meet the Panel's criteria, and the agency finds these studies adequate to support a prophylaxis claim for tolnaftate. Although the study by Smith, Dickson, and Knox does not meet the Panel's 12-week criteria, the results of the study can be considered supportive of the other two studies discussed above.

The agency disagrees with the comment's request to abandon a distinction between treatment and prophylaxis for antifungals. Treatment of an existing fungal condition and prevention of a condition are clearly different clinical entities. The intended use of the antifungal drug is different in each instance. Likewise, there is no reason to drop the prophylaxis indication for tolnaftate. This use has been satisfactorily established by the clinical data cited above.

However, the agency is revising the heading for § 333.250(b)(2), as suggested by the comment, so that it is consistent with the style and format of the other headings in the tentative final monograph.

#### References

- (1) Charney, P., V. M. Torres, A. W. Mayo, and E. B. Smith, "Tolnaftate as a Prophylactic Agent for Tinea Pedis," *International Journal of Dermatology*, 12:179-185, 1973.
- (2) Burrill, B. B., and A. S. Nemlick, "Prophylaxis of Tinea Pedis," *Journal of the Medical Society of New Jersey*, 67:629-631, 1970.
- (3) Smith, E. B., J. E. Dickson, and J. M. Knox, "Tolnaftate Powder in Prophylaxis of Tinea Pedis," *Southern Medical Journal*, 67:776-778, 1974.

(4) Comment No. RC0002, Docket No. 80N-0476, Dockets Management Branch.

#### M. Comments on Undecylenates

20. One comment contended that under proper application of the governing scientific and legal standards FDA must conclude that the undecylenates are safe and effective for both treatment and prevention of athlete's foot, jock itch, and ringworm. The comment maintained that by definition an effective antifungal drug kills fungi and, with daily use, prevents the onset of infection. According to the comment, there is no evidence that fungi, unlike bacteria, develop resistance to topical agents, and separate prophylaxis studies are unnecessary to sustain prophylaxis claims. However, if separate evidence of prophylactic effect is to be required, the comment stated that such evidence has already been submitted to the agency for undecylenates (Ref. 1). In this study by Sulzberger and Kanof, 1,364 patients who received no treatment were compared with 1,213 patients treated with undecylenates. The researchers found that 28 percent of the untreated patients developed signs and symptoms of athlete's foot, but that only 4 percent of those on undecylenates developed the disease (Ref. 1). A reply comment reiterated the points made in the initial comment.

Another reply comment stated that the study of undecylenates by Sulzberger and Kanof (Ref. 1) falls quite short of the Panel's criteria to establish a prophylactic claim and gave the following reasons:

- (1) No accurate record was made of actual treatment periods.
- (2) No mycology was performed on any of the subjects. The only criterion was presence or absence of clinical symptoms.
- (3) The control group received "no prophylactic agent" rather than a placebo vehicle control. This factor is especially important in a prophylactic study because the vehicle and proper hygiene make a significant contribution in the prevention of athlete's foot infections.

Another comment submitted new data consisting of the results of a study conducted with an undecylenate powder to prevent athlete's foot (Ref. 2). According to the comment, this study was designed in accordance with the Panel's recommendations, and the results of the study demonstrate the prophylactic effectiveness of undecylenates.

The Panel recognized that many Category I drugs effective in the treatment of athlete's foot might also be

effective in its prevention. However, the Panel believed that data from human studies were necessary to support a prophylactic indication. The long-term effects of prophylactic drugs on the feet and on the fungi that cause athlete's foot are also not known. Accordingly, the agency concurs with the Panel that separate prophylaxis studies are necessary to support prophylactic claims.

With regard to the undecylenates, the agency concurs with the Panel and the reply comment that the study by Sulzberger and Kanof (Ref. 1), submitted to support a prevention claim for undecylenates, has the following serious deficiencies: The length of treatment was unclear; no potassium hydroxide (KOH) preparations or cultures were done; and the control group was "no treatment" controlled rather than "placebo vehicle" controlled.

The study submitted by the comment enrolled 97 subjects, some with and some without a history of athlete's foot; all had no lesions, negative cultures, and negative KOH preparations. Active drug (20 percent zinc undecylenate and 2 percent undecylenic acid) and vehicle were used in a double-blind manner. After 6 weeks of twice daily therapy, visual examination was performed on all patients and KOH preparations and cultures were done on those with lesions. Eight patients with positive mycological findings at week 6 were counted as prophylaxis failures and placed on therapy. All eight patients had been receiving the vehicle. Four other patients were dropped from the study for failing to appear at week 6. The remaining patients were kept on therapy until week 12, when cultures and KOH preparations were performed on all patients. No drug-related adverse effects were reported. The study, which included both 6-week and 12-week prophylaxis failures, concluded that infection occurred in 28 percent of the untreated groups, while infection occurred in only 7 percent of the treated group.

The agency has reviewed the study and finds that it does not provide sufficient evidence to support a claim for the effectiveness of undecylenates in the prevention of athlete's foot. A major flaw in this trial was the decision to perform mycological evaluations at week 6 only on those patients with visible foot lesions and to drop from the study those patients with positive mycology. Had mycological evaluations been done on all patients at week 6, additional failures (positive mycology but no clinical symptoms) might have been detected and the difference

[Code of Federal Regulations]  
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TITLE 21--FOOD AND DRUGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES--Continued

PART 333--TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE--Table o

Subpart C--Topical Antifungal Drug Products

Sec. 333.201 Scope.

Source: 58 FR 49898, Sept. 23, 1993, unless otherwise noted.

(a) An over-the-counter antifungal drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in Sec. 330.1 of this chapter.

(b) Reference in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[Code of Federal Regulations]  
[Title 21, Volume 5, Parts 300 to 499]  
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TITLE 21--FOOD AND DRUGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES--Continued

PART 333--TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE--Table o

Subpart C--Topical Antifungal Drug Products

Sec. 333.203 Definitions.

As used in this subpart:

- (a) Antifungal. A drug which inhibits the growth and reproduction of fungal cells and decreases the number of fungi present.
- (b) Athlete's foot. An infection of the feet caused by certain dermatophytic fungi.
- (c) Dermatophyte. A fungus that invades and lives upon the skin or in the hair or nails.
- (d) Fungus. Any of a large division of plants, including dermatophytes, yeasts, and molds, characterized by a simple cell structure and the absence of chlorophyll.
- (e) Jock itch. A chronic and recurrent infection caused by certain dermatophytic fungi; affects the upper, inner thighs and sometimes extends to the groin and the pubic area; the condition most frequently occurs in men, but may also occur in women.
- (f) Ringworm. A skin infection caused by certain dermatophytic fungi.

[Code of Federal Regulations]  
[Title 21, Volume 5, Parts 300 to 499]  
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TITLE 21--FOOD AND DRUGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES--Continued

PART 333--TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE--Table o

Subpart C--Topical Antifungal Drug Products

Sec. 333.210 Antifungal active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

- (a) Clloquinol 3 percent
- ✓(b) Haloprogin 1 percent
- ✓(c) Miconazole nitrate 2 percent.
- ✓(d) Povidone-iodine 10 percent.
- ✓(e) Tolnaftate 1 percent.
- (f) Undecylenic acid, calcium undecylenate, copper undecylenate, and zinc undecylenate may be used individually or in any ratio that provides a total undecylenate concentration of 10 to 25 percent.

[Code of Federal Regulations]  
[Title 21, Volume 5, Parts 300 to 499]  
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TITLE 21--FOOD AND DRUGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES--Continued

PART 333--TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE--Table o

Subpart C--Topical Antifungal Drug Products

Sec. 333.250 Labeling of antifungal drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antifungal."

(b) Indications. The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1)(i) of this section and may contain the additional phrase listed in paragraph (b)(1)(ii) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established in paragraph (b) of this section, may also be used, as provided in Sec. 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for

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introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) For products containing any ingredient identified in Sec. 333.210 labeled for the treatment of athlete's foot, jock itch, and ringworm. (i) (Select one of the following: "Treats," "For the treatment of," "For effective treatment of," "Cures," "For the cure of," "Clears up," or "Proven clinically effective in the treatment of") (select one condition from any one or more of the following groups of conditions:

- (A) "Athlete's foot," "athlete's foot (dermatophytosis)," "athlete's foot (tinea pedis)," or "tinea pedis (athlete's foot)";
- (B) "Jock itch," "jock itch (tinea cruris)," or "tinea cruris (jock itch)"; or
- (C) "Ringworm," "ringworm (tinea corporis)," or "tinea corporis (ringworm)."

(ii) In addition to the information identified in paragraph (b)(1)(i) of this section, the labeling of the product may contain the following statement: (Select one of the following: "Relieves," "For relief of," "For effective relief of," or "Soothes,") (select one or more of the following: "Itching," "scaling," "cracking," "burning," "redness," "soreness," "irritation," "discomfort," "chafing associated with jock itch," "itchy, scaly skin between the toes," or "itching, burning feet").

(2) For products containing the ingredient identified in Sec. 333.210(e) labeled for the prevention of athlete's foot. (i) (Select one of the following: "Clinically proven to prevent," "Prevents," "Proven effective in the prevention of," "Helps prevent," "For the prevention of," "For the prophylaxis (prevention) of," "Guards against," or "Prevents the recurrence of") (select one of the following: "Athlete's foot," "athlete's foot

(dermatophytosis), " "athlete's foot (tinea pedis)," or "tinea pedis (athlete's foot)" "with daily use."

(i) In addition to the information identified in paragraph (b) (2) (i) of this section, the labeling of the product may contain the following statement: "Clears up athlete's foot infection and with daily use helps keep it from coming back."

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) For products containing any ingredient identified in Sec. 330.210. (i) "Do not use on children under 2 years of age unless directed by a doctor."

(ii) "For external use only."

(iii) "Avoid contact with the eyes."

(2) For products labeled according to paragraph (b) (1) of this section for the treatment of athlete's foot and ringworm. "If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor."

(3) For products labeled according to paragraph (b) (1) of this section for the treatment of jock itch. "If irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a doctor."

(4) For products labeled according to paragraph (b) (2) of this section for the prevention of athlete's foot. "If irritation occurs, discontinue use and consult a doctor."

(5) For products containing the ingredient identified in Sec. 333.210(a) labeled according to paragraph (b) (1) of this section. The following statements must appear in boldface type as the first warnings under the "Warnings" heading. (i) "Do not use on children under 2 years of age." [This warning is to be used in place of the warning in paragraph (c) (1) (i) of this section.]

(ii) "Do not use for diaper rash."

(d) Directions. The labeling of the product contains the following statements under the heading "Directions":

(1) For products labeled according to paragraph (b) (1) of this section for the treatment of athlete's foot, jock itch, and ringworm. [Select one of the following: "Clean" or "Wash"] "the affected area and dry thoroughly. Apply" (the word "spray" may be used to replace the word "apply" for aerosol products) "a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer.

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consult a doctor. This product is not effective on the scalp or nails."

(2) For products labeled according to paragraph (b) (2) of this section for the prevention of athlete's foot. "To prevent athlete's foot," (select one of the following: "clean" or "wash") "the feet and dry thoroughly. Apply" (the word "spray" may be used to replace the word "apply" for aerosol products) "a thin layer of the product to the feet once or twice daily (morning and/or night). Supervise children in the use of this product. Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

**2 November 2004**

**Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Drive  
Rockville, Maryland 20857**

**Dear Dockets Manager,**

**Please find enclosed a CITIZENS PETITION requesting a change in Food & Drug regulations.**

**This petition was prepared using instructions obtained from the FDA web page.**

**Accordingly 4 sets are enclosed all are signed by the petitioner.**

**Respectively submitted,**

**Francis W. Busch  
Executive Vice President  
Prostrong Inc  
860 945 9469  
[FrankB@prostrong.com](mailto:FrankB@prostrong.com)**

