Since the State statute requires that loan brokers include their fees in calculating the finance charge and annual percentage rate in cases where the creditor would exclude such fees in calculating those same items, the Board proposes to determine that the State disclosure requirement is preempted in those instances where the State law would require the use of the same term to disclose a different amount than would be disclosed under Federal law. The Board recognizes that the State disclosure serves a useful purpose in informing consumers about costs that they may incur in such credit transactions. The Board, however, believes that the approach chosen by the State will confuse consumers who will receive two different sets of figures, described by the same terminology. In such cases, it appears that the State disclosure would contradict the disclosures required under Federal law and interfere with the intent of the Federal scheme.

(5) Comment Requested

Interested persons are invited to submit comments regarding the proposed determination. Since this request concerns a State law governing disclosures by loan brokers, who are not considered "creditors" and therefore are not themselves subject to the requirements of Regulation Z, the question arises as to whether the State law is subject to the Board's preemption authority. (See § 226.28(a) of Regulation Z, which provides that "a State law is inconsistent if it requires a creditor to make disclosures * * * that contradict the requirements of the Federal law.") Although the Board, in the past, has made preemption determinations concerning laws whose coverage may extend to parties who are not considered creditors for purposes of Regulation Z (for example, Arizona in 1985 and South Carolina in 1983), the Board specifically requests comment on this issue. The Board has assumed, however, for purposes of this proposed determination, that the law in question is subject to the Board's preemption authority. After the close of the comment period and analysis of the comments received, notice of final action on the proposal will be published in the **Federal Register.**

List of Subjects in 12 CFR Part 226

Advertising, Banks, Banking, Consumer protection, Credit, Federal Reserve System, Finance, Penalties, Truth in Lending.

Board of Governors of the Federal Reserve System, August 31, 1987.

William W. Wiles,

Secretary of the Board.

[FR Doc. 87-20388 Filed 9-3-87; 8:45 am]

BILLING CODE 6210-01-M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 107

Small Business Investment Companies; Extension of Comment Period on Proposed Rulemaking

AGENCY: Small Business Administration.

ACTION: Notice of extension of comment period on proposed rulemaking.

SUMMARY: On August 4, 1987, the Small Business Administration (SBA) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) regarding an increase in the examination fees imposed upon small business investment companies (see 52 FR 28842).

That publication provided that comments on the NPRM would be received for a period of 30 days from the date of publication. This Notice extends the comment period pertaining to the NPRM for an additional 30 days to allow the public more time to consider this proposal.

DATE: Comments on the above-referenced proposed rule should be submitted in duplicate by October 3, 1987.

ADDRESS: Written comments should be addressed to: Robert G. Lineberry, Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street NW., Room 808, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: John L. Werner, Director, Office of Investment, (202) 653-6584.

SUPPLEMENTARY INFORMATION: In order to provide more time for public comment on the above-referenced proposed rule, SBA is hereby extending the comment period relative to the proposal for an additional 30 days. The public is encouraged to supply written comments to the address indicated above so that a complete record can be established in this rulemaking.

Date: August 29, 1987.

James Abdnor,

Administrator.

[FR Doc. 87-20417 Filed 9-3-87; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 352

[Docket No. 78N-0038]

Discussion of Appropriate Testing Procedures for Over-the-Counter Sunscreen Drug Products; Public Meeting and Reopening of the Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Public meeting and reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a public meeting will be held to discuss recommendations of the Advisory Review Panel on Over-the-Counter (OTC) Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products regarding final product testing (i.e., testing procedures for determination of the sun protection factor (SPF) value and related claims) of OTC sunscreen drug products. The meeting will be structured to discuss the specific topics and to seek answers to the specific questions listed in this notice.

DATES: Meeting date January 26, 1988; Time 9:00 a.m. The agency anticipates that the meeting will last one day. However, if there is sufficient interest in participation, the meeting will be extended an additional day at the discretion of the chairperson. Relevant data and notice of participation by December 3, 1987. Administrative record to remain open until April 26, 1988. Comments regarding matters raised at the meeting by April 26, 1988.

ADDRESSES: Relevant data, notice of participation, and comments to the Dockets Management Branch, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857. Meeting to be held in Conference Rooms D and E, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Saul Bader or Jeanne Rippere, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md 20857, 301-295-8003.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 25, 1978 (43 FR 38206), FDA published an advance notice of proposed rulemaking on OTC sunscreen drug products based on the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products. In that report, the Panel

recommended final product testing of each sunscreen drug product. In its recommended monograph, the Panel included testing procedures for the determination of the sun protection factor (SPF) value and of related labeling claims for all sunscreen drug products containing Category I (generally recognized as safe and effective) ingredients (43 FR 38265 to 38267). The Panel included these testing procedures to assure the uniform evaluation of all sunscreen products.

In response to the Panel's report; the agency received a number of comments regarding statistical and technical aspects of the sunscreen product testing procedures (Refs. 1 through 9). The comments questioned these aspects of the testing procedures and offered many suggestions, ranging from requiring a minimum of 8 subjects per test (Ref. 2) to proposing alternated statistical methods for evaluating the test data (Refs. 2 and 7). One technical aspect of the sunscreen testing procedures is the use of an 8 percent standard homosalate formulation to validate a laboratory's testing methods. The agency believes that data submitted to the Panel and the agency on the 8 percent standard homosalate formulation (Refs. 6, 9, and 10) are too variable to estimate accurately the SPF of this formulation. The agency believes that it is necessary to analyze more data on the 8 percent homosalate formulation before officially designating this formulation as the standard formulation.

The Panel's recommendations represent a first attempt to standardize testing for sunscreen drug products, and many technical issues are left to be resolved. Because the testing procedures for sunscreen drug products will be included in the agency's tentative final monograph, the agency feels that it is important to try to resolve the majority of these issues regarding sunscreen testing before the tentative final monograph is proposed.

In addition, the agency is aware that, recently, a number of sunscreen drug products have been marketed with SPF values greater than 15, which was the Panel's highest classifiction. The agency believes that consideration needs to be given to modifying the Panel's recommended monograph in order to address these higher SPF values. However, to date, no data on products with such SPF values have been submitted to the rulemaking for OTC sunscreen drug products, and the agency is not able to make any determinations regarding such products.

Therefore, under 21 CFR 10.65, the agency has concluded that it would be in the public interest to hold an open public meeting to discuss these and related issues. The agency is inviting interested individuals or groups to discuss these and related issues at an open meeting to be held on January 26 1988.

Topics and questions to be considered during the meeting include:

1. Procedures and Statistical Methods

Are the Panel's proposed general procedures and statistical methods for sunscreen testing valid? Some comments questioned the soundness of the Panel's proposed procedures and statistical methods for determining the SPF and the Product Category Designations (PCD) of a sunscreen drug product (Refs. 2 and 7). One comment (Ref. 2) suggested categorizing a product into a PCD on the basis of a 90 percent confidence interval computed for the product's mean SPF. To categorize a product into a particular PCD, the entire confidence interval would have to fall within the range of values included in that PCD. The other comment (Ref. 7) suggested the use of binomial (nonparametric) analysis instead of parametric analysis of sunscreen testing data.

Based upon the comments and because the testing procedures represent a first attempt to standardize sunscreen testing methods, the agency believes that it may be necessary to revise the Panel's proposed testing procedures. However, the agency believes that the confidence interval procedure suggested by the first comment may be too stringent for use in assigning PCD's because the criterion of having the entire confidence interval fall within the PCD would never, or only rarely, be satisfied. For example, if the true mean SPF is 6, then 90 percent of the time the confidence interval will straddly two PCD's (i.e., moderate (SPF of 4 to 6) and extra (SPF of 6 to 8)).

The agency believes that the binomial procedure suggested by the second comment has merit, but that the binomial procedure may not be as statistically powerful as the procedure described below, which involves a confidence interval for the mean SPF.

Therefore, in this notice, the agency is setting forth for comment two different approaches to analyzing the data generated by sunscreen drug product testing. The first method utilizes the testing procedures proposed by the Panel but adds one step to the determination of the PCD. The added step is equivalent to performing a one-sided t test at the 0.05 level of significant where the null hypothesis is that the mean SPF is less than the minimal SPF of the assigned PCD.

The full statistical procedure would be as follows: First, select at least 20 subjects, with n representing the number of subjects selected, and for each subject compute the SPF value in the manner described in the Panel's report (43 FR 38213). Second, compute the mean SPF value, $\bar{x}$, and the standard deviation, s, for these subjects. Third, obtain the upper 5 percent point from the t distribution with $n-1$ degrees of freedom. Denote this value by little t. Fourth, compute $ts/\sqrt{n}$. Let this quantity be denoted by A (i. e., $A=ts/\sqrt{n}$). Fifth and last, the drug product is classified into a PCD as follows: if $15+A\leq\bar{x}$, the PCD is Ultra; if $8+A\leq\bar{x}<15+A$, the PCD is Maximal; if $6+A\leq\bar{x}<8+A$, the PCD is Extra; if $4+A\leq\bar{x}<6+A$, the PCD is Moderate; if $2+A\leq\bar{x}<4+A$, the PCD is Minimal; if $\bar{x}<2+A$, the PCD is Below Minimal. (Note: The procedure proposed by the Panel has $A=0$ which is equivalent to a test of hypothesis with the level of significant equal to 0.50.)

The above fifth step can also be written in the following equivalent fashion: if $15\leq\bar{x}-A$, the PCD is Ultra; if $8\leq\bar{x}-A<15$, the PCD is Maximal; if $6\leq\bar{x}-A<8$, the PCD is Extra; if $4\leq\bar{x}-A<6$, the PCD is Moderate; if $2\leq\bar{x}-A<4$, the PCD is Minimal; if $\bar{x}-A<2$, the PCD is Below Minimal.

The following numerical example is provided: Take 20 subjects with a mean SPF value of 6.40 and a standard deviation of 1.60. Here $n=20$, $\bar{x}=6.40$, $s=1.20$, and the standard error is $s/\sqrt{n}=1.2/\sqrt{20}=0.268$. The procedure proposed by the Panel would stop here and classify the product in the PCD "Extra" ($6\leq\bar{x}<8$). The procedure set forth above goes one step further by testing whether the observed mean of 6.4 really reflects a true population mean of at least 6. To do this testing, the third to fifth steps, outlined above would be carried out as follows: The upper 0.05 point from the t distribution with 19 degrees of freedom is 1.729. The A value of the fourth step is $A=1.729(0.268)=0.46$. The mean SPF value minus A is $\bar{x}-A=6.40-0.46=5.94$. We thus find $\bar{x}-A$ satisfies the $4\leq\bar{x}-A<6$ interval ($4<5.94<6$). Thus, the product would be classified as "Moderate." The observed mean value of 6.40 is not significantly large enough to establish that the true population means SPF value is 6 or larger.

The second method that the agency is proposing concentrates on the boundaries between the PCD's rather than on the actual SPF values of the sunscreen drug product. After the minimal erythema dose for unprotected

skin (MED(US)) has been established (see 43 FR 38213), the protected skin is tested at exposure times chosen so that the corresponding SPF's are slightly less than the lower bounds of the intervals defining the various PCD's. For example, the protected skin could be tested at 1.9 x MED(US), 3.9 x MED(US), 5.9 x MED(US), 7.9 x MED(US), and 14.9 x MED(US). Thus, if a subject's MED(US) were 1.5, the subject's protected skin exposure times would be 2.85(=1.9x1.5), 5.85(=3.9x1.5), 8.85(=5.9x1.5), 11.85(=7.9x1.5) and 22.35(=14.9x1.5). For each subject who experiences erythema, the calculated "SPF" (being the minimal erythema dose of the protected skin (MED(PS) divided by the MED(US)) would be either 1.9, 3.9, 5.9, 7.9, or 14.9. If a subject's "SPF," calculated in this manner, is 5.9, then that subject received Moderate (i.e., 4 to less than 6) protection and is assigned a score of 4, the lower bound of the interval defining the Moderate PCD. Thus, a subject with a calculated "SPF" of 1.9 is not in any of the PCD's and is assigned a 0; an "SPF" of 3.9 is in the Minimal PCD and is assigned a 2; an "SPF" of 5.9 is in the Moderate PCD and is assigned a 4; an "SPF" of 7.9 is in the Extra PCD and is assigned a 6; an SPF of 14.9 is in the Maximal PCD and is assigned an 8; and if erythema is not found on the protected skin at 14.9 x MED(US), then the product is in the Ultra PCD and is assigned a 15.

This procedure does not distinguish between SPF's in the same PCD such as 4.1, 4.5, 5.0, or 5.9. It does distinguish between SPF's in different PCD's, such as 5.9 and 6.1. The agency considers this procedure's ability to make this distinction important because products are labeled in terms of their PCD, not their SPF. Thus, there is no need to distinguish between two products whose true SPF's are 4.1 and 5.9 because they are both labeled as Moderate. However, there is a need to distinguish between two products whose true SPF's are 5.9 and 6.1 because the former is labeled as Moderate, and the latter is labeled as Extra.

The PCD assigned to a test preparation is the largest PCD for which one would, using a one-sided binomial test at $p = 0.5$, reject the hypothesis that the probability is not greater than 50 percent that an individual will receive the protection of the assigned PCD. This procedure is the same as assigning the largest PCD for which the lower limit of a 95 percent confidence interval on the percentage of subjects that received protection at least as great as that defining the PCD exceeds 50 percent.

In a panel of 20 subjects, the product is assigned the PCD corresponding to the sixth smallest score (disregarding ties) from among the 20 subjects. In a panel of 25 subjects, the product is assigned the PCD corresponding to the eighth smallest score. A few examples are shown below.

Product 1:
2 2 2 4 4 *6* 6 6 6 6 6 8 8 8 8 8 8

Product 2:
0 0 2 2 4 *4* 4 4 4 6 6 6 6 6 6 6 6 6

Product 3:
4 4 4 4 4 6 6 *8* 8 8 8 8 8 8 8 8 15 15 15 15 15

Product 1 would be assigned the Extra PCD, Product 2 the Moderate PCD, and Product 3 the Maximal PCD.

The agency is requesting comments on the Panel's proposed procedure for sunscreen testing as well as on the two methods outlined above.

2. Standard Formulation

The agency's evaluation of the Panel's report and of the comments received has raised some questions regarding the use of the 8 percent homosalate formulation as the standard for the validation of sunscreen product testing. Results from two collaborative studies that were designed to establish an SPF value for a standard sunscreen formulation, each study involving six participating laboratories, were submitted to the Panel and to the agency (Refs. 6, 9, and 10). The standard sunscreen formulation used in these studies was an 8 percent homosalate formulation that was endorsed by the Panel for use as a standard in such testing. In the collaborative studies, however, the results obtained by the laboratories involved were inconsistent, producing SPF values that place the 8 percent homosalate standard formulation into different PCD's. The agency believes that the variability of the SPF values obtained in these studies demonstrates that the SPF and PCD of the 8 percent homosalate standard formulation have not been precisely established and may be incorrect. Therefore, the agency is asking whether new data have become available since the 8 percent homosalate standard formulation was originally tested that would provide additional information regarding the reliability of the 8 percent homosalate standard formulation. If such data are available, they should be submitted to the agency.

The agency is also concerned about using a standard preparation that may have a relatively low SPF of 4 to validate a sunscreen testing procedure that is supposed to determine a wide range of SPF's (currently SPF 2 up to SPF 30). Would standard formulations with SPF values higher than 4 make the determination of SPF values higher than 8 and 15 more accurate? The agency believes that two or three standard preparations should be available having SPF's that represent the entire range of possible SPF's (e.g., SPF 8 and SPF 20 or SPF 4, SPF 15, and SPF 25). Are sunscreen preparations with relatively high SPF values available that would be appropriate for use as standard preparations when testing sunscreen drug products with estimated SPF's greater than 15? Data on such preparations should be submitted.

3. Number of Subjects.

The Panel recommended that groups of twenty subjects should be used for each test panel but added that "the standard error shall not exceed +5 percent of the mean. An appropriate number of additional subjects shall be used to determine the PCD, if a PCD does not fall within the limits of the standard error." Comments submitted to the agency (Refs. 2, 5, and 11) revealed substantial confusion regarding the standard error criterion proposed by the Panel. Additionally, one comment suggested that determination of the SPF of a sunscreen could be accurately done with only 8 subjects.

The agency believes that the number of subjects for a test panel should be fixed before the test and should not be changed. The sample size must be large enough to give a sense that it is not a unique, atypical subset of the target population. The agency believes that 20 subjects is the minimum number of subjects that may be used to make a test panel.

Regarding the standard error criterion for determining the precision of an assay, the agency believes that the data submitted to the Panel do not support use of the standard error. Furthermore, because the agency is proposing more elaborate statistical calculations for determining SPF's and PCD's, the standard error criterion is no longer necessary. Therefore, the agency is considering revising the Panel's recommended § 352.42(g) as follows: "Number of subjects. Groups of at least 20 subjects shall be used for each test panel. The panel size shall be fixed in advance and additional subjects shall not be added."

The agency invites comment on this possible change. If this change is not acceptable, what is the best method for evaluating sunscreen test data to determine if additional subjects are needed to obtain a valid SPF value?

What is the minimum number of subjects required?

4. Exposure Times

The Panel's protocol for sunscreen testing calls for a geometric series of increments in ultraviolet (UV) exposures (e.g., 1, 1.25, 1.56, 1.96, and 2.44 minutes). One comment (Ref. 5) recommended the use of time increments smaller than 25 percent. Other comments (Refs. 1, 4, and 6) recommended shorter time intervals and the use of an arithmetic rather than geometric progression of UV doses for the determination of SPF values above 8.

The agency believes that there is little justification for a geometrically increasing series of time intervals. Geometrically increasing intervals offer less precision in the upper ranges, and precision has become increasingly important because of the appearance on the OTC market of sunscreens with SPF values much higher than 15 (i.e., up to 30). Conversely, the MED can be measured with equal precision across the full range of an arithmetically arranged series of exposure times.

The agency believes that exposure times are crucial to the accurate determination of SPF values and PCD's. Therefore, FDA is considering revising the discussion of the determination of SPF value using an artificial light source in proposed § 352.43 to state:

A series of UV light exposures (units of time) are administered to the subsite areas on each subject with a solar simulator. One series of exposures shall be administered to the untreated, unprotected skin to determine the subject's inherent MED (MED (US)). The time intervals selected shall be an arithmetic series with 11 exposures, increasing in 4 second increments, beginning with 10 seconds and ending with 50 seconds (i.e., 10, 14, 18, 22, 26, 30, 34, 38, 42, 46, and 50 seconds). This series would be suitable for a normal person exposed to a 150-watt xenon lamp solar simulator. Usually the MED of a subject's unprotected skin is determined the day before the testing of a product. The protected test sites (standard sunscreen and test sunscreen product) usually are exposed to UV light the next day. [NOTE: The foregoing procedure is applicable only for the PDC determination based on the lower confidence limit for the mean SPF. The protected skin exposure times appropriate for the PCD determination based on the lower confidence limit for the percentage of patients that receive a given level of protection has already been specified.] The exact series of exposures to be given shall be determined by the MED of the unprotected skin and the expected SPF of the test product. There should be at least 11 exposures. The difference between successive exposure times should be consistent. The exposure times should be densely clustered around the expected MED of the protected skin (MED(PS)). Preliminary testing using more widely spaced exposure times may be necessary to roughly determine an expected SPF value. The increment interval (I) for the series of UV exposures of the protected skin is determined from the MED(US) and the upper and lower limit of the expected testing range of SPF values. Each expected SPF has a testing range of SPF values defined by a lower value (L) and an upper value (U). The following example is provided for guidance:

Expected SPF	Testing range of SPF, L to U
2	1 to 5.
4	3 to 7.
6	5 to 10.
8	6 to 12.
15	10 to 18.
22	16 to 24.
30	25 to 35.

Based on the above, the exposure times for an expected SPF would be calculated as follows:

L×MED(US); L×MED(US)+I;
L×MED(US)+2I; L×MED(US)+3I; . . .
L×MED(US)+10I, where

$$I = \frac{U \times MED(US) - L \times MED(US)}{10}$$

and MED (US) is the observed MED (US) value from the previous day. For example, if the MED (US) is 30 seconds, and the product being tested has an expected SPF of 8, then L=6 and U=12. From these values, the interval (I) can be computed as follows:

$$I = \frac{U \times MED\ (US) - L \times MED\ (US)}{10} = \frac{12 \times 30 - 6 \times 30}{10} = 18$$

Thus the increment used to establish the exposure times is 18 seconds. Therefore, the calculated exposure times would be as follows:

L×MED (US)=180 seconds
L×MED (US)+I=180+18=198 seconds
L×MED (US)+2I=216 seconds
L×MED (US)+3I=234 seconds
L×MED (US)+4I=252 seconds
L×MED (US)+5I=270 seconds
L×MED (US)+6I=288 seconds
L×MED (US)+7I=306 seconds
L×MED (US)+8I=324 seconds
L×MED (US)+9I=342 seconds
L×MED (US)+10I=360 seconds

At 16 to 24 hours after exposure, the shortest exposure time must produce no effect (i.e., no erythema) on the skin. The longer exposure times should produce light and moderately red exposure sites. The MED is the time of exposure the produces the minimally perceptible erythema at 16 to 24 hours postexposure. The SPF value of the test sunscreen is then the ratio of the exposure time interval required to produce the MED of the protected skin to the exposure time interval required to produce the MED of the unprotected skin (control site) as follows:

$$\text{SPF value} = \frac{MED\ (PS)}{MED\ (US)}$$

5. Amount of Sunscreen.

In its report, the Panel recommended that the amount of test sunscreen and the standard sunscreen per application should be 2 miligrams (mg) or 2 microliters (ul) per square centimeter (cm^2). An expert on sunscreen testing procedures who is not affiliated with FDA suggested to the agency that 1 mg/cm^2 rather than 2 mg/cm^2 is a more appropriate amount of sunscreen to use in the sunscreen testing procedure because 1 mg/cm^2 more accurately reflects the amount of sunscreen drug product normally used by a consumer (Ref. 12). The agency notes that use of 1 mg/cm^2 would undoubtedly produce lower SPF values and believes that this may be a way to accommodate the new higher SPF values because using 1 mg/cm^2 of the product may produce SPF value that more closely approximate the time a product will provide protection. Is 2 mg/cm^2 an appropriate amount of sunscreen product to use for the testing procedure?

6. SPF Value Higher Than 15

According to the Panel's report (43 FR 38267 and 38268), a product containing active sunscreen ingredients that provide an SPF of 15 or greater may be labeled as an "Ultra Sun Protection Product (15)—stay in the sun 15 times as long as before without sunburning." The Panel recommended that such products be allowed the following indications, among others: (1) "Affords the most protection against sunburn;" (2) "provides the highest degree of sunburn

protection. . . ;" and (3) "provides the highest degree of sunscreen protection* * *" What benefit is provided to the consumer by sunscreen drug products claiming to have SPF values greatly in excess of 15 (i.e., 23 or even 30) if, as the Panel claims, SPF 15 offers the maximum possible protection? Can these higher SPF values be accurately determined using currently available sunscreen testing procedures? Companies marketing such products should provide supporting data. If the currently recognized sunscreen testing procedures are not adequate, what tests are necessary to determine SPF values higher than 15?

7. Product Category Designations

The agency notes that the Panel's recommended Product Category Designations do not adequately accommodate sunscreen drug products with high SPF values of 25 or 30. If products having SPF values much higher than 15 are determined to be rational, how should the Panel's recommended PCD's be modified to include these higher SPF values?

One example might be as follows:

PCD	SPF
Minimal	2 to under 4.
Moderate	4 to under 8.
Extra	8 to under 12.
Maximal	12 to under 20.
Ultra	20 and above.

8. "Sweat Resistant," "Water Resistant," and "Waterproof" Labeling

The agency notes that the Panel's recommended criteria for a sunscreen drug product to be labeled as "sweat resistant," "water resistant," or "waterproof" are based on the product's ability to maintain its original PCD after testing procedures that are specified for each of the above three claims. The agency believes that there are situations in which the Panel's recommendation could lead to labeling that would be misleading to the consumer. For example, a product in the Moderate PCD ($4 \leq SPF < 6$) that maintained its PCD after 40 minutes of water immersion could be labeled "water resistant," whereas a product in the Ultra PCD ($15 \leq SPF$) that fell into the Maximal PCD ($8 \leq SPF < 15$) after the water immersion could not. The fact that the latter product would provide more sun protection after immersion than would the former would not be reflected by the Panel's labeling proposal. One way of avoiding such a situation involves labeling a product with a PCD established under the ordinary test conditions and with a PCD established under the "sweat resistant," "water resistant," or "waterproof" test conditions. The agency is requesting comments on this situation or other possible solutions to this problem.

Because the final formulation of a sunscreen drug product affects the performance of the active ingredient in the product, the agency concludes that testing procedures for sunscreen drug products are necessary. It is important for the safe and effective use of these products by consumers that these testing procedures result in labeling that accurately reflects the characteristics of a particular sunscreen formulation. Consumers should have assurance that using any sunscreen displaying an SPF value of 8 will indeed provide protection in the sun for 8 times longer than using no sunscreen. An inaccurately labeled sunscreen may cause a consumer to remain in the sun too long and may result in a painful burn. The long effects of using an improperly labeled sunscreen could include premature aging of the skin and skin cancer.

The agency requests information on the recommended sunscreen testing procedures from any interested person. Any individual or group wishing to submit data relevant to the questions above should send them on or before December 3, 1987 to Docket No. 78N–0038, Dockets Management Branch, Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Any individual or group wishing to make a presentation at the meeting should contact Saul Bader or Jeanne Rippere, Division of OTC Drug Evaluation (HFN-210), Office of Drug Standards, Center for Drugs and Biologics, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8003. Interested persons who wish to participate must also send a notice of participation on or before December 3, 1987 to the Dockets Management Branch (address above). All notices submitted should be identified with the docket number found in brackets in the heading of this notice and should contain the following information: Name; address; telephone number; business affiliation, if any, of the person desiring to make a presentation, and the approximate amount of time requested for the presentation.

Groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. After reviewing the notices of participation, FDA will notify each participant of the schedule and time allotted to each person.

The administrative record of the OTC sunscreen drug products rulemaking is being reopened to specifically include only the proceedings of this pubic meeting. The administrative record will remain open until April 26, 1988, to allow comments on matters raised at the meeting.

References

(1) *Comment No. C00004,* Dockets No. 78N–0038, Dockets Management Branch.
(2) *Comment No. C00008,* Dockets No. 78N–0038, Dockets Management Branch.
(3) *Comment No. C00009,* Dockets No. 78N–0038, Dockets Management Branch.
(4) *Comment No. C00016,* Dockets No. 78N–0038, Dockets Management Branch.
(5) *Comment No. C00031,* Dockets No. 78N–0038, Dockets Management Branch.
(6) *Comment No. C00046,* Dockets No. 78N–0038, Dockets Management Branch.
(7) *Comment No. C00049,* Dockets No. 78N–0038, Dockets Management Branch.
(8) *Comment No. C00075,* Dockets No. 78N–0038, Dockets Management Branch.
(9) *Comment No. SUP002,* Dockets No. 78N–0038, Dockets Management Branch.
(10) *OTC Volume 060169,* Dockets No. 78N–0038, Dockets Management Branch.
(11) *Comment No. C00068,* Dockets No. 78N–0038, Dockets Management Branch.
(12) Memorandum from J. Rippere to S, Bader, dated December 3, 1986, coded M00001, Dockets No. 78N–0038, Dockets Management Branch.

Dated: August 25, 1987.

John A. Norris,

Acting Commissioner of Food and Drugs.

[FR Doc. 87–20377 Filed 9–3–87; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 41

[LR–33–87]

Excise Taxes; Reduction of Heavy Vehicle Use Tax for Foreign-Based Vehicles

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations portion of this issue of the **Federal Register,** the Internal Revenue Service is issuing temporary regulations relating to the imposition of the heavy vehicle use tax on foreign-based highway motor vehicles. The temporary regulations also serve as the text for this Notice of Proposed Rulemaking.