

interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace extending upward from 700 feet above the surface (AGL) at Grundy, VA. A GPS RWY 22 SIAP has been developed for Grundy Municipal Airport. Additional controlled airspace extending upward from 700 feet above the surface (AGL) is needed to accommodate this SIAP and for IFR operations at the airport. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace extending upward from 700 feet above the surface are published in Paragraph 6005 of FAA Order 7400.9C, dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 14 CFR 11.69.

§ 17.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, dated August 17, 1995, and effective September 16, 1995, is proposed to be amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the Earth.

* * * * *

AEA VA E5 Grundy, VA [New]

Grundy Municipal Airport, VA
(lat. 37°13'56" N, long. 82°07'30" W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Grundy Municipal Airport.

* * * * *

Issued in Jamaica, New York, on August 5, 1996.

John S. Walker,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 96-20832 Filed 8-14-96; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. 78N-0038]

RIN 0910-AA01

Discussion of the Photochemistry and Photobiology of Sunscreens; Public Meeting and Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting and reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to obtain data and information on the photochemistry and photobiology of sunscreens. Meeting attendees are invited to address issues described in this notice. In addition, FDA is reopening the administrative record for the proposed rulemaking for over-the-counter (OTC) sunscreen drug products to allow for comment on matters considered in this notice and at the meeting. This meeting is part of the ongoing review of OTC drug products conducted by FDA.

DATES: The meeting will be held on September 19 and 20, 1996, 8:30 a.m. Submit notice of participation by September 6, 1996. Submit comments regarding matters discussed in this

notice or raised at the meeting by December 6, 1996. The administrative record will remain open until December 6, 1996.

ADDRESSES: Submit notice of participation, and written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The meeting will be held at the Doubletree Hotel, Plaza I and II, 1750 Rockville Pike, Rockville, MD 20852, 301-468-1100.

FOR FURTHER INFORMATION CONTACT: Donald Dobbs, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222, FAX 301-827-2316.

SUPPLEMENTARY INFORMATION:

I. Background

The agency believes that the use of sunscreen products is helpful as a component of a regimen for sun protection. A joint panel of the American Academy of Dermatology and the Centers for Disease Control and Prevention recently recommended the use of sunscreen products in addition to limiting exposure to ultraviolet (UV) radiation, wearing protective clothing, avoiding artificial tanning devices, and seeking shade when your shadow is shorter than your height (Ref. 1).

The agency is not at this time proposing to amend the tentative final monograph for OTC sunscreen drug products published on May 12, 1993 (58 FR 28194), and this notice does not intend to imply concerns about sunscreen agents as a class. However, recent scientific advances in understanding of the photochemistry and photobiology of sunscreen active ingredients have raised issues for discussion regarding use of sunscreen ingredients singly and in combinations; specifically, about zinc oxide and titanium dioxide. The agency is seeking to incorporate these recent scientific advances into the base of regulatory information supporting the final monograph for OTC sunscreen drug products.

II. Request for Data and Information

A. Photostability and photobiology of titanium dioxide and zinc oxide

In the Federal Register of August 25, 1978 (43 FR 38206), the agency published an advance notice of proposed rulemaking to establish a monograph for OTC sunscreen drug products based on the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn,

and Sunburn Prevention and Treatment Drug Products (the Panel). In its report (43 FR 38206 at 38250), the Panel stated that titanium dioxide is recognized as an effective opaque chemical for use as a physical sunscreen because it reflects and scatters both UV (290 to 400 nanometers (nm)) and visible light (400 to 700 nm) radiation, rather than absorbing the rays, thereby providing a barrier for sun-sensitive individuals. The Panel concluded that titanium dioxide was both safe and effective for sunscreen use. The Panel classified zinc oxide as an inactive ingredient (43 FR 38206 at 38208) and did not review it for safety and effectiveness.

In the tentative final monograph for OTC sunscreen drug products (58 FR 28194), the agency concurred with the Panel's recommendation on titanium dioxide and proposed to classify it as a Category I (generally recognized as safe and effective) sunscreen used alone or in combination with other Category I sunscreens (58 FR 28194 at 28295 to 28296). The agency reviewed the data on zinc oxide that had been submitted to the Panel (one study) and other available data and concluded that the data were insufficient to determine effectiveness. The agency classified zinc oxide as a Category III (available data are insufficient to classify as safe and effective and further testing is required) sunscreen (58 FR 28194 at 28213). The agency is currently evaluating additional effectiveness data to support Category I status for zinc oxide in the final monograph for OTC sunscreen drug products.

There has been a renewed interest in incorporating titanium dioxide and zinc oxide in sunscreen formulations because these ingredients may confer protection for a broad range of the UV spectrum. In addition, ultra-fine forms of these ingredients have been developed that are more esthetically pleasing (Refs. 2, 3, and 4).

Sunscreens have been generally classified as chemical (organic) or physical (inorganic), depending on whether they absorb specific wavelength bands of UV radiation or reflect and scatter UV radiation. Although titanium dioxide and zinc oxide have been described as chemically inert ingredients that attenuate through reflection and scattering, new data and information indicate that they also absorb UV radiation, as well as scatter visible light (Ref. 5). Various authors (Refs. 5 through 10) have shown that these ingredients exhibit a semiconductor optical absorption gap. They absorb most radiation at wavelengths shorter than the gap (approximately 380 nm) and

scatter radiation at wavelengths longer than the gap. When titanium dioxide and zinc oxide are irradiated with light containing energy greater than the gap (approximately 3 electron volts), an electron from the valence band can be excited to the conduction band, thus creating an electron-hole pair. Because of these semiconductor properties, titanium dioxide and zinc oxide have been used as photocatalysts to degrade organic substances and pesticides in the environment (Refs. 11 through 15). In addition, titanium dioxide is being currently developed as a photooxidative self-cleaning and/or biocidal coating for industrial surfaces (Ref. 16).

In vitro, it has been demonstrated that titanium dioxide in the presence of UV radiation can be cytotoxic to certain cancer cells (HeLa cells and T-24 human bladder cancer cells) even though titanium dioxide or UV radiation alone were nontoxic under study conditions (Refs. 17 and 18). Because these cells are transformed cell lines and are not normal human cells, the relevance of these in vitro findings to sunscreen use by humans (i.e., in sunlight) is not known for zinc oxide and titanium dioxide.

Mineral components, particle size, surface area, crystalline structure, particle coatings, pH of the medium, differences in the refractive index of medium, and other properties of the formulation may affect the photocatalyst properties of titanium dioxide (Refs. 2 through 5 and 19 through 22). These characteristics are not mentioned in the United States Pharmacopeia (USP) compendial monographs, which contain no discussion of trace ions that may affect the absorption band gap between the valence and conduction bands or electronic energy levels, e.g., the range of wavelengths that are absorbed.

The agency would like to receive information and data that address the following issues: (1) Characterize the potential systemic absorption and long-term safety of the topical application of titanium dioxide and/or zinc oxide in sunscreen drug products; (2) ascertain whether titanium dioxide and/or zinc oxide in sunscreen drug products can, under conditions of combination with certain ingredients, time, temperature, and/or exposure to water, photocatalyze. If so, determine whether this occurs at a rate such that the effectiveness of the sunscreen drug products would be significantly reduced; and (3) determine whether current compendial monograph specifications are sufficient to ensure manufacture of safe and effective titanium dioxide and/or zinc oxide in sunscreen drug products.

B. Photochemistry and photobiology of sunscreen ingredients alone and in combination

In the advance notice of proposed rulemaking for OTC sunscreen drug products (43 FR 38206), the Panel recommended that 21 ingredients be considered generally recognized as safe and effective as OTC sunscreens. Based on the available data, the Panel determined that these sunscreens could be used alone or in any combination (without reference to final formulation) as long as the finished product has a minimum sun protectant factor (SPF) of 2. For the majority of these ingredients, the available data consisted of short-term animal and human toxicity studies on individual ingredients in the absence of UV radiation.

In the tentative final monograph for OTC sunscreen drug products (58 FR 28194), the agency concurred with most of the Panel's recommendations and classified 20 of the 21 ingredients as Category I sunscreens when used alone or in combination with other Category I sunscreens (58 FR 28194 at 28295 to 28296). Padimate A was classified as Category II (concentrations 5 percent or higher) and Category III (concentrations less than 5 percent) on the basis of data and information on its phototoxicity that was not available to the Panel at the time of its review (58 FR 28194 at 28211).

Consumers' increased awareness of the need to protect themselves against the harmful effects of both UVA (320 to 400 nm) and UVB (290 to 320 nm) radiation has created a demand for sunscreen products with higher SPF's and better broad-spectrum (290 to 400 nm) protection of longer duration. Manufacturers have responded by creating products with higher SPF's that claim to provide protection against both UVA and UVB radiation. Manufacturing products with such characteristics often requires that the products contain combinations of several Category I sunscreen ingredients (usually three or more) that absorb over different parts of the UV spectrum.

The agency is interested in the photostability of sunscreen ingredients and the effects that a lack of stability could have on these sunscreen products. Some sunscreen ingredients may undergo photodegradation (Refs. 23 through 29), producing byproducts which may affect product safety or effectiveness (Refs. 30 through 35). Photodegradation of some active sunscreen ingredients may occur in the presence of certain inactive ingredients (Refs. 36 and 37).

Therefore, the agency is interested in photostability methodologies for sunscreen ingredients. The agency would like to know how to test the photostability of sunscreen ingredients and to characterize potential byproducts in sunscreen product combinations and in different formulations.

The agency is interested in data and information on the following issues: (1) The potential of active sunscreen ingredients, alone and in combination, to interact in the presence of UV radiation and/or certain inactive ingredients; (2) characterization of potential byproducts of such interactions and description of impact, if any, on safety or effectiveness of final sunscreen formulations; and (3) descriptive measurement methods and characterization of local or possible systemic effects in vivo.

The agency has concluded that it would be in the public interest to hold a public meeting, in accordance with 21 CFR 10.65, to discuss the issues associated with the photochemistry and photobiology of sunscreens. The proposed rulemaking for OTC sunscreen drug products involves 21 CFR parts 352, 700, and 740; however, the discussion at the public meeting will be limited to proposed part 352, i.e., sunscreens for use as OTC drugs.

Any individual or group interested in making a presentation at the meeting should contact Donald Dobbs (address above). Presentations should only address the issues listed in this notice. Persons interested in participating in the meeting must also send a notice of participation on or before September 6, 1996, to the Dockets Management Branch (address above). All notices of participation 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, summary of the 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. Depending on the time available and the number of participants, 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 for the OTC sunscreen drug products rulemaking is being reopened to specifically allow for

comments on matters raised in this notice and at the meeting. The agency requests data and information regarding the photochemistry and photobiology of sunscreens from any interested person. Any individual or group may, on or before December 6, 1996, submit to the Dockets Management Branch (address above), comments and data specifically limited and relevant to the issues in this notice or addressed at the meeting. Two copies of any comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the docket number found in brackets in the heading of this document. The administrative record will remain open until December 6, 1996.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Goldsmith, L., et al., "Proceedings from the National Conference to Develop a National Skin Cancer Agenda," *Journal of the American Academy of Dermatology*, 34:822-3, 1996.
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8. Harbour, J. H., J. Tromp, and M. L. Hair, "Photogeneration of Hydrogen Peroxide in Aqueous TiO₂ Dispersions," *Canadian Journal of Chemistry*, 63:204-208, 1985.
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14. Mak, M. K. S., and S. T. Hung, "Degradation of Neat and Commercial Samples of Organophosphate Pesticides in Illuminated TiO₂ Suspensions," *Toxicology and Environmental Chemistry*, 36:155-168, 1992.
15. Borello, R., et al., "Photocatalytic Degradation of DDT Mediated in Aqueous Semiconductor Slurries by Simulated Sunlight," *Environmental Toxicology and Chemistry*, 8:997-1002, 1989.
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17. Cai, R., et al., "Induction of Cytotoxicity by Photoexcited TiO₂ Particles," *Cancer Research*, 52:2346-2348, 1992.
18. Kubota, Y., et al., "Photokilling of T-24 Human Bladder Cancer Cells With Titanium Dioxide," *British Journal of Cancer*, 70:1107-1111, 1994.
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21. Ortyl, T. T., and G. E. Peck, "Surface Charge of Titanium Oxide and Its Effect on Dye Adsorption and Aqueous Suspension Stability," *Drug Development and Industrial Pharmacy*, 17:2245-2268, 1991.
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Dated: August 9, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-20856 Filed 8-14-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 31, 35a, 301, 502, 503, 509, 513, 514, 516, 517, 520 and 521

[INTL-062-90; INTL-0032-93; INTL-52-86; INTL-52-94]

RIN 1545-AO27; 1545-AR90; 1545-AL99; 1545-AT00

General Revision of Regulations Relating to Withholding of Tax on Certain U.S. Source Income Paid to Foreign Persons and Related Collection, Refunds, and Credits; Revision of Information Reporting and Backup Withholding Regulations; and Removal of Regulations Under Part 35a and of Certain Regulations Under Income Tax Treaties; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains corrections to the notice of proposed rulemaking (INTL-062-90; INTL-0032-93; INTL-52-86; INTL-52-94) which was published in the Federal Register for Monday, April 22, 1996 (61 FR 17614). The notice of proposed rulemaking relates to the withholding of income tax under sections 1441 and 1442 on certain U.S. source income paid to foreign persons, the related tax deposit and reporting requirements under section 1461, and the related collection, refunds, and credits of withheld tax under sections 1461 through 1463 and section 6402. In addition, the notice of proposed rulemaking also relates to the statutory exemption under sections 871(h) and 881(c) for portfolio interest. The notice of proposed rulemaking proposes to remove certain temporary employment tax regulations under the Interest and Dividend Compliance Act of 1983 and to amend existing regulations under sections 6041A and 6050N. The notice of proposed rulemaking also proposes changes to proposed regulations contained in project number INTL-52-86, published on February 29, 1988 (53 FR 5991) under sections 6041, 6042, 6045, and 6049. The document proposes related changes to the regulations under sections 163(f), 165(j), 3401, 3406, 6114, and 6413 and proposes further changes to the proposed regulations under section 6109 contained in project number IL-0024-94 published on June 8, 1995 (60 FR 30211). The document proposes to remove certain regulations under income tax treaties.

FOR FURTHER INFORMATION CONTACT:

Philip Garlett, (202) 622-3880 for questions on proposed regulations under sections 1441, 1442, 1461, 1462, 1463, 3401, 6402, and 6413; Gwendolyn Stanley, (202) 622-3860 for questions on payments to partnerships; Carl Cooper, (202) 622-3840 for questions on proposed regulations under section 163(f), 165(j), 871(h) and 881(c) and on withholding agreements; Teresa Burrige Hughes, (202) 622-3880 for questions on proposed regulations under section 6041 through 6049, 6050N; Teresa Burrige Hughes, (202) 622-3880 and Renay France, (202) 622-4910 for questions on proposed regulations under section 3406; Elissa Shendalman, (202) 622-3870 on proposed regulations under sections 6045 and 6049 relating to the reporting of payments made in a currency other than the U.S. dollar or transactions subject to section 988; Lilo Hester, (202) 874-1490 for questions on proposed regulations under section 6109; David F. Bergkuist, (202) 622-3860 for questions

on proposed regulations under section 6114 (numbers are not toll-free).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking that is the subject of these corrections are under sections 163(f), 165(j), 871, 881, 1441, 1442, 1461, 1462, 1463, 3401, 3406, 6041, 6041A, 6042, 6045, 6049, 6050N, 6109, 6114, 6402, and 6413 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking (INTL-062-90; INTL-0032-93; INTL-52-86; INTL-52-94) contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (INTL-062-90; INTL-0032-93; INTL-52-86; INTL-52-94) which is the subject of FR Doc. 96-8936 is corrected as follows:

1. On page 17619, column 1, in the preamble following the paragraph heading "*Section 1.165-12 Denial of Deduction for Losses on Registration-Required Obligations Not in Registered Form*", the last line in the first paragraph is corrected to read "in Section 35a.9999-4T, A-5 that the person is not a U.S. person.", and the italicized heading preceding the second paragraph is removed.

2. On page 17621, column 1, in the preamble following the paragraph heading "*Section 1.1441-1 Requirement for the Withholding of Tax on Payments to Foreign Persons*", line 16 from the top of the column, the language "continue to apply trusts. See § 1.1441-" is corrected to read "continue to apply to trusts. See § 1.1441-".

3. On page 17621, column 3, in the preamble following the paragraph heading "*Section 1.1441-1 Requirement for the Withholding of Tax on Payments to Foreign Persons*", the second full paragraph, line 3 from the bottom of the paragraph, the language "§ 1.9999-5(b), A9 and that are proposed" is corrected to read "§ 35a.9999-5(b), A-9 and that are proposed".

4. On page 17626, column 3, in the preamble following the paragraph heading "*Section 1.1441-4 Certain Exemptions From Withholding*" the first full paragraph, line 11, the language "(which expired on February, 1993). A" is corrected to read "(which expired on February 2, 1993). A".

5. On page 17628, column 2, in the preamble under the paragraph heading "*Section 1.1441-7 General Provisions Relating to Withholding Agents*", the