(2) For the purposes of these mandatory inspections, piece-part opportunity means:

(i) The part is completely disassembled when done in accordance with the disassembly instructions in the engine manufacturer's Heavy Maintenance Manual; and

(ii) The part has accumulated more than 100 cycles in service since the last piece-part opportunity inspection, provided that the part was not damaged or related to the cause for its removal from the engine.''

(b) Except as provided in paragraph (c) of this AD, and notwithstanding contrary provisions in § 43.16 of the Federal Aviation Regulations (14 CFR 43.16), these mandatory inspections shall be performed only in accordance with the Airworthiness Limitations Section of the Allison Engine Company AE 3007A and AE 3007C Engine Manuals.

Alternative Methods of Compliance

(c) 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 Engine Certification Office (ECO). Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector (PMI), who may add comments and then send it to the 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.

Ferry Flights

(d) Special flight permits may be issued in accordance with §§ 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 accomplished.

Continuous Airworthiness Maintenance Program

(e) FAA-certificated air carriers that have an approved continuous airworthiness maintenance program in accordance with the record keeping requirement of § 121.369 (c) of the Federal Aviation Regulations (14 CFR 121.369 (c)) must maintain records of the mandatory inspections that result from revising the Airworthiness Limitations Section and the air carrier's continuous airworthiness program. Alternately, certificated air carriers may establish an approved system of record retention that provides a method for preservation and retrieval of the maintenance records that include the inspections resulting from this AD and include the policy and procedures for implementing this alternate method in the air carrier's maintenance manual required by § 121.369 (c) of the Federal Aviation Regulations (14 CFR 121.369 (c)). However, the alternate system must be accepted by the appropriate PMI and require the maintenance records be maintained either indefinitely or until the work is repeated. Records of the piece-part inspections are not required under § 121.380 (a) (2) (vi) of the Federal Aviation Regulations (14 CFR 121.380 (a) (2) (vi)). All other operators must maintain the records of mandatory inspections required by the applicable regulations governing their operations.

Note 3: The requirements of this AD have been met when the engine manual changes are made and air carriers have modified their continuous airworthiness maintenance plans to reflect the requirements in the engine manuals.

Effective Date

(f) This amendment becomes effective on August 7, 2000.

Issued in Burlington, Massachusetts, on June 2, 2000.

David A. Downey,

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

[FR Doc. 00–14441 Filed 6–7–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 352, and 700

[Docket No. 78N–0038]

RIN 0910–AA01

Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Extension of Effective Date; Reopening of Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of effective date; reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is extending to December 31, 2002, the effective date for the final monograph for over-the-counter (OTC) sunscreen drug products that published in the **Federal Register** of May 21, 1999 (64 FR 27666). The final monograph established conditions under which OTC sunscreen drug products are generally recognized as safe and effective and not misbranded. The extension of the effective date applies to all OTC sunscreen drug products that would be regulated under parts 310, 352, and 700 (21 CFR parts 310, 352, and 700). In addition, FDA is reopening the administrative record for the rulemaking for OTC sunscreen drug products to allow for comment specifically on the information requested in this document. FDA is taking this action in response to a citizen petition requesting that the agency, among other things, initiate an administrative process to publish a ''comprehensive'' sunscreen final monograph that addresses formulation, labeling, and testing requirements for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection.

DATES: *Effective date:* The effective date of the amendments to parts 310, 352, and 700 in the regulation published at 64 FR 27666, May 21, 1999, is delayed until December 31, 2002. The amendment in this final rule to § 310.545 is effective December 31, 2002.

Compliance dates: For products with annual sales less than $25,000 compliance is December 31, 2003. For all other OTC drug products compliance is December 31, 2002.

Comment date: Submit written comments by September 6, 2000. The administrative record will remain open until September 6, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 12, 1993 (58 FR 28194), the agency published a notice of proposed rulemaking in the form of a tentative final monograph (TFM) for OTC sunscreen drug products. The TFM proposed the conditions under which sunscreen drug products would be considered generally recognized as safe and effective, under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)), and not misbranded under section 502 of the act (21 U.S.C. 352).

The TFM proposed labeling for products that claim to protect against UVB radiation and discussed the types of labeling claims that could be used for products that contain UVA-absorbing ingredients. The TFM included a list of proposed sunscreen active ingredients, including ingredients that were believed to have absorption spectra extending into the UVA range.

The TFM proposed a set of testing procedures for measuring a product's sun protection factor (SPF). The SPF value measures the performance of sunscreens that absorb erythema-causing UV radiation, but does not fully describe a product's UVA protection. As the agency acknowledged in the TFM, ''currently there is no generally acceptable method for determining a

meaningful UVA protection factor that is analogous to the SPF'' (58 FR 28194 at 28249).

Following publication of the TFM, the agency continued to work closely with interested parties to develop standardized UVA testing procedures and an accurate, helpful way to present information about UVA protection in product labeling. The agency held a public meeting, on May 12, 1994, to discuss UVA testing procedures. The agency also reopened the administrative record to allow additional submissions on UVA-related issues until July 31, 1994 (59 FR 16042, April 5, 1994).

In the **Federal Register** of September 16, 1996 (61 FR 48645) and October 22, 1998 (63 FR 56584), the agency amended the TFM to add the UVA-absorbing sunscreen ingredients avobenzone and zinc oxide to the proposed list of monograph ingredients. The agency proposed indications for these ingredients, such as ''provides broad spectrum protection'' and ''provides protection from the UVA rays that may contribute to skin damage and premature aging of the skin'' (61 FR 48645 at 48655 and 63 FR 56584 at 56589).

On November 21, 1997, Congress enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA section 129 provided as follows:

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.

Section 129 of FDAMA prompted FDA to identify those parts of the TFM for OTC sunscreen drug products that could be finalized within the timeframe set by FDAMA. In late 1997, FDA was still working on the development of testing standards and labeling for UVA radiation protection. As recently as January 27, 1999, the agency held a public meeting to continue developing UVA testing methods and labeling (Ref. 1). Given these outstanding issues, the agency decided to address the FDAMA deadline by finalizing the UVB portions of the monograph (and related provisions on water resistant test methods and cosmetic labeling).

In the **Federal Register** of May 21, 1999 (64 FR 27666), FDA published a final rule in the form of a final monograph for OTC sunscreen drug products. The monograph included 16 active ingredients, required labeling for products that contain one or more of these active ingredients, a standardized test for measuring SPF values, and standard methods for measuring the water resistant properties of sunscreens. The monograph included modifications to the agency's general OTC drug product labeling rule in § 201.66 (21 CFR 201.66) to accommodate certain sunscreen drug products that are packaged in small containers, are intended to be applied to limited areas of the face, and otherwise meet the factors discussed in the OTC drug product labeling rule for monograph-specific modifications (64 FR 27666 at 27681 to 27682 and 64 FR 13254 at 13270). The monograph did not, however, address active ingredients, labeling, and test methods for products intended to provide UVA protection.

The agency set a 2-year effective date (May 21, 2001) for part 352 and the related nonmonograph conditions in § 310.545(a)(29). The agency also set a 2-year effective date for new § 700.35, which addresses cosmetic products that contain sunscreen active ingredients for nontherapeutic, nonphysiologic uses (e.g., as a color additive or to protect the color of the product). The agency set a 1-year effective date (May 22, 2000) for new § 740.19 (21 CFR 740.19), which addresses a warning statement for cosmetic suntanning preparations that do not contain a sunscreen active ingredient. The extension of the effective date in this document does not apply to § 740.19.

II. Citizen Petition

Prior to publication of the sunscreen final rule, a citizen petition (Ref. 2) requested the agency, among other things, to initiate an administrative process for publishing a ''comprehensive'' sunscreen final monograph that addresses formulation, labeling, and testing for both UVB and UVA radiation protection.

On July 22, 1999, the agency held a public meeting to hear the views of interested parties regarding the sunscreen final monograph (Ref. 3). At the meeting, the petitioner requested that FDA defer the effective date of the final rule until 2 years after it completes a comprehensive final monograph that includes UVA radiation protection. After several subsequent meetings with the agency (Ref. 4), the petitioner proposed that a 19-month extension of the effective date of the sunscreen final monograph would be sufficient time for it to submit the appropriate data to assist FDA in completing a comprehensive final monograph in time for a target December 2002 effective date.

FDA granted the petition in part by agreeing to extend the effective date of the monograph to December 31, 2002, with the expectation that appropriate data would be received within a reasonable timeframe so that a comprehensive UVA–UVB monograph could be issued in advance of that date. Accordingly, the agency is issuing this document to extend the effective date of the sunscreen final monograph for the reasons set forth in its October 1, 1999, response to the citizen petition (Ref. 5). Copies of the petition and the agency's response are on file in the Dockets Management Branch (address above) and are available through a freedom of information request.

III. Process for Completion of a Comprehensive Final Monograph

The agency has requested at public meetings on January 27, July 22, and October 26, 1999 (Refs. 1, 3, and 6, respectively), and in letters of July 16, and September 2, 1999, and March 20, 2000, to the petitioner (Refs. 7, 8, and 9, respectively), the type of specific data and information that would be helpful for the completion of a comprehensive final monograph for OTC sunscreen drug products. These data and information concerned: (1) Testing and labeling of high SPF products, (2) testing and labeling for UVA radiation protection and, (3) integration of UVA and UVB indications for use and performance statements. To date, the agency has received only a portion of this requested information (Ref. 9). As part of this reopening of the administrative record, the agency is including the above information and any other information submitted to the sunscreen docket related to the completion of a comprehensive UVA–UVB final monograph.

In order to complete a comprehensive final monograph by the target December 31, 2002, effective date, the agency intends to move forward and publish a proposed rule for a comprehensive final monograph, receive comments on that proposal, and issue a final rule by December 31, 2001. That final rule would then have a 1-year effective date of December 31, 2002. Therefore, in order not to delay this process, the agency has determined that all data and information to be considered for the proposed rule must be received by the close of the administrative record as stated in this document. After the administrative record closes on September 6, 2000, the agency will use the information in the administrative record to prepare a proposed rule for a comprehensive final monograph for OTC sunscreen drug products. The agency has determined that 90 days provides industry with a reasonable amount of time to prepare and submit the data requested in this document.

IV. Request for Comment

The agency stated in the sunscreen final rule that SPF values above 30 are not supported at this time and that sunscreen drug products with SPF values above 30 should be limited to one collective term, i.e., SPF 30 ''plus'' or ''+'' (64 FR 27666 at 27675). While the agency believes that the sunscreen final monograph test procedures for measuring SPF values up to 30 represent a straightforward, well-understood, and sound method for measuring these values, a number of comments submitted in response to the May 12, 1993, tentative final monograph for OTC sunscreen drug products (58 FR 28194) questioned the ability of current testing methods to accurately and reproducibly determine SPF values for high SPF (i.e., above SPF 30) sunscreen drug products (64 FR 27666 at 27680).

Most of the comments' concerns related to potential interlaboratory variation when utilizing SPF test methodology. Primary concerns included the potential for overestimation of high SPF values due to the spectra of currently used solar simulators and the need for one or more high SPF standard sunscreens (i.e., as laboratory controls). Long radiation exposures necessitated by SPF values well above 30 and the use of a relatively low SPF laboratory control may significantly increase the potential for decreased interlaboratory accuracy and reproducibility for high SPF sunscreen drug products. The agency invited interested persons to continue developing the test methods needed to measure high SPF values and to provide FDA data to support such methods. The agency is currently evaluating data and information subsequently received from two comments (Refs. 10 and 11) concerning this issue.

In the final rule, the agency discussed the difficulty in explaining the nonlinearity (i.e., percent reduction in erythemogenic UV radiation) of the SPF rating system in the limited space on a product label (64 FR 27666 at 27675). The agency also invited interested persons to consider proposed methods for communicating in labeling the level of protection associated with high SPF values. To date, the agency has not received any proposals relative to the labeling of sunscreens with high SPF values.

After review of the comments concerning the adequacy of current testing procedures for determining high SPF numbers, the agency has identified eight areas in which it seeks additional data and information. The agency is requesting further comment in these areas to provide interested parties the opportunity to submit data and information to address these issues. It is not necessary to resubmit data and information previously provided to the agency. A cross-reference to an earlier submission will be sufficient.

A. Solar Simulator Spectral Power Distribution

The agency has received several comments, including a recent citizen petition (Ref. 10), suggesting the adoption of a spectral power distribution that specifies the proportion of erythema-effective radiation in a table format. The comments suggested that the spectra of currently used solar simulators (especially around 290 nanometers (nm) and above 350 nm) could cause overestimation of SPF values for high SPF sunscreens. Because shorter wavelengths can make a very large contribution to erythema, the comments stated that small errors in the 290 nm region of solar simulator spectra could have considerable effects. In addition, the comments noted that spectral power deficiencies above 350 nm may give artificially high SPF values for sunscreen drug products that absorb poorly in the long wavelength UVA region. The comments suggested that the agency replace the specifications in § 352.71 of the sunscreen monograph that state ''sun at a zenith angle of 10½'' and ''less than 1 percent shorter than 290 nm'' with the European Cosmetic, Toiletry, and Perfumery Association (COLIPA) table of ''percent erythemal contribution'' (Ref. 10) as the spectral power distribution standard for the light source used in the SPF test procedures.

The agency is requesting comment on whether the solar simulator spectral distribution specifications contained in the COLIPA standard are appropriate for use in SPF testing procedures. The agency would also like comment on a potential modification of the standard that would modify the erythema-effective radiation contribution of wavelengths below 290 nm to less than 0.1 percent (to prevent overestimation of SPF values). The agency believes that this specification is readily obtainable with commercially available cut-off filters. In addition, the agency is interested in comment concerning the practicality of lowering the below-290 nm specification to 0.01 percent. Therefore, a solar simulator using the following modification of the COLIPA standard for determining the SPF of a sunscreen drug product would be filtered so that it provides a continuous emission spectrum from 290 to 400 nm with the following percentage of erythema-effective radiation in each specified range of wavelengths:

TABLE 1.—SOLAR SIMULATOR EMISSION SPECTRUM

Wavelength Range (nm)	Percent Erythemal Contribution
< 290	< 0.1
290–310	46.0–67.0
290–320	80.0–91.0
290–330	86.5–95.0
290–340	90.5–97.0
290–350	93.5–99.0

B. Thermal Overloading of the Skin

The testing of high SPF sunscreen drug products necessitates longer exposure times than testing of lower SPF values. Such increases in irradiance levels have the potential to produce thermal overloading of the skin and influence the UV radiation dose reciprocity relationship (and therefore SPF values). The comments suggested that limits such as 1,250 to 1,500 watts/meter^2 be placed on the total irradiance delivered to the skin for all wavelengths. Several comments, including a recent citizen petition (Ref. 10), also suggested that the ''out of band'' specification in § 352.71 of the sunscreen monograph (i.e., that not more than 5 percent of a solar simulator's total energy output can be contributed by wavelengths longer than 400 nm) is not obtainable from many devices currently utilized for evaluating sunscreens.

The agency considers it important to limit total energy delivered to the skin

so that skin temperature does not reach a point that influences the UV dose reciprocity relationship when encountering the long exposure times necessary to test high SPF sunscreen drug products. The agency is requesting comment on whether replacing the ''out of band'' specifications in § 352.71 with a limit on total solar simulator irradiance for all wavelengths may be an appropriate modification of current testing procedures that will improve the testing of high SPF sunscreens. In addition, the agency is also requesting comment on an appropriate irradiance limit for this modification.

C. High SPF Standard Sunscreen

The agency received several comments suggesting that standard sunscreens (i.e., controls) with SPF values of 15 or higher be developed for testing high SPF sunscreen drug products. Studies submitted by the comments tend to support the conclusion that a specific control(s) may be needed to accurately test high SPF sunscreen drug products. However, these studies lacked sufficient numbers of subjects, did not address suitability of a standard across different laboratories, and did not document the following properties required in a standard sunscreen: (1) Low level of interlaboratory variation, (2) sensitivity to experimental error, and (3) ease of preparation with a reasonable degree of accuracy.

One comment supplied ''round-robin,'' collaborative SPF testing data from 7 laboratories on 153 subjects, with 2 possible SPF 15 standard sunscreens, ''Formulation A'' and ''Formulation B'' (Refs. 12 and 13). The agency believes that the data could support ''Formulation B'' as an appropriate SPF 15 standard sunscreen if additional information is submitted and found acceptable. Because the formulation was supplied to all laboratories by a single source, there are no data to demonstrate that multiple laboratories can prepare, assay, and utilize the standard successfully. Further, the standards were not analyzed by the spectrophotometric method in § 352.70(c) of the sunscreen monograph, but rather by an alternate proposed method (see section IV.D of this document). The agency is requesting the submission of the additional data necessary to document the suitability of Formulation ''B'' and the analytical method.

In addition, the agency is requesting comment and any supporting data and information concerning the need for additional standard sunscreens (with SPF values higher than 15) as well as the use of specific standard sunscreens for specific ranges of SPF values (i.e., bracketing).

D. High-Performance Liquid Chromatography (HPLC) Assay

As discussed in section IV.C of this document, data supplied in support of an SPF 15 standard sunscreen preparation included the use of an HPLC assay instead of the spectrophotometric assay in § 352.70(c). The comment suggested that the HPLC protocol is now commonly used by analytical laboratories for the assay of sunscreen formulations (and that it can also be used for the homosalate standard sunscreen). The agency invites specific comment and data from analytical laboratories as to which assay method they use and why they use that particular method.

Before the agency can evaluate the HPLC method supplied with the SPF 15 standard sunscreen data, method validation data are necessary. The agency is requesting a validation package that documents specificity, accuracy, limit of detection, linearity, precision, and reproducibility of the method. The agency is especially concerned that the presence of any impurities (particularly UV radiation-absorbing impurities) in the standard sunscreen and product formulations can be detected by the HPLC method, because interfering substances could affect the SPF determination. The validation package should include chromatograms and demonstrate that the HPLC method is suitable for both the SPF 4 (homosalate) and SPF 15 standards (or other standard sunscreens, if appropriate). The chemistry guideline entitled ''Reviewer Guidance, Validation of Chromatographic Methods'' explains these requirements in greater detail and is available on the agency's Internet website for the Center for Drug Evaluation and Research (CDER) (http://www.fda.gov/cder/guidance/index.htm), or may be obtained from the Drug Information Branch (HFD–211), CDER, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573.

E. Number of Test Subjects

Several comments suggested that the ''limitation'' of 20 to 25 subjects in the SPF test in § 352.72(g) may be an issue for sunscreen drug products with high SPF values due to potential for high variability in the responses obtained. The comments indicated that more than 20 to 25 subjects may be necessary. The agency is requesting data and information on the testing of SPF values over 30 in relation to this issue and suggestions for an appropriate number of test subjects to be used in such testing.

F. Exposure Doses

Determination of the minimal erythemal dose on protected skin (MED(PS)) is described in § 352.73(c) of the SPF testing procedures as follows:

* * * A series of seven exposures shall be administered to the protected test sites to determine the MED of the protected skin (MED(PS)). The doses selected shall consist of a geometric series of five exposures, where the middle exposure is placed to yield the expected SPF plus two other exposures placed symmetrically around the middle exposure. * * *

The agency proposed this format in the tentative final monograph (58 FR 28194 at 28269 to 28272), in the context of SPF values up to 30, because of its concern that a widely-spaced geometric progression offers less accuracy and precision in the upper SPF ranges and may produce overestimation of the true SPF. Exposure dose intervals in the above geometric series decrease as expected SPF values increase.

The agency is requesting comment and any supporting data and information concerning the adequacy of the current exposure dose format in the testing of sunscreen drug products claiming to have SPF values over 30.

G. Labeling

In the sunscreen final rule (64 FR 27666 at 27675), the agency stated that the nonlinearity (i.e., percent reduction in erythemogenic UV radiation) of the SPF rating system is a concept difficult to explain in the limited space on a product label. The agency noted the relatively small difference in additional sunburn protection for most people provided by SPF 30 and SPF 50 sunscreens in terms of their absorption of erythemal UV radiation. The agency has a continuing concern about consumers' perception and understanding of the difference in screening abilities between, for example, an SPF 4 and SPF 15 as opposed to an SPF 30 and SPF 50.

The agency is concerned that an average sunscreen consumer may ascribe more to high SPF values than is clinically relevant and that such products may further encourage the use of sunscreens as a safe way to prolong sun exposure. The concept of increasing SPF values has been described in the context of increasing the time for which a person could be exposed to the sun without burning. While such a description may be true, it omits

essential information about skin cancers and photoaging that may occur from different (i.e., nonerythemogenic) wavelengths and/or at suberythemal doses of UV radiation in the erythemogenic wavelength region. Sunscreen use alone will not prevent all of the possible harmful effects of the sun for all consumers, even with the use of high SPF sunscreen drug products. Variation between individuals, UV radiation absorption and substantivity of sunscreen drug products, exposure conditions, and conditions of use (e.g., inadequate application/reapplication) preclude a precise result for each individual. Sunscreens are part of a sun protection program in which it is clear that the goal is to limit sun exposure even with the use of a sunscreen. Without adequate labeling, high SPF numbers may dilute the desired public health message. In addition, previously submitted labeling comprehension data, which were discussed at a public meeting (Ref. 14), indicated a fair amount of confusion concerning consumer comprehension of the SPF rating system.

The agency is requesting comment on any proposed methods for meaningfully communicating in product labeling the level of sun protection associated with high SPF sunscreen drug products. In addition to this information, the agency is also requesting comment relative to the use of professional labeling (and what that labeling might state) specifically to provide high SPF value information to health professionals.

H. Technical and Human Limitations

The agency is aware that the testing of sunscreen drug products with high SPF values necessitates the use of longer ultraviolet radiation exposure times. Such exposures can result in test subjects remaining in front of the light source for several hours, especially when a standard sunscreen and water resistance test are also included (Ref. 11).

Considering the generally available SPF test equipment currently used in testing laboratories, the agency is requesting comment on the practical human limitations of the test relative to high SPF values. Is the determination of an SPF value routinely practicable for SPF values of, for example, 60 or higher? What total exposure times would be involved at such SPF levels? What is the practical limit in terms of the SPF value?

V. Comment on the Extension of the Effective Date

In its October 1, 1999, citizen petition response (Ref. 5), the agency set forth in detail its finding that a stay of the effective date for the sunscreen final monograph, until December 31, 2002, would be in the public interest. Since the agency is extending the effective date of the sunscreen final monograph based on the citizen petition response, it finds, for good cause, that this extension of the effective date of the final monograph does not require further notice and comment procedures (5 U.S.C. 553(b)). More than 6 months have passed since the agency issued the petition response and the agency has received no adverse correspondence or comments with respect to its decision. Therefore, the agency is now extending the effective date of the final rule. However, in accordance with 21 CFR 10.40(e)(1), the agency will accept comment on this extension for a period of 90 days.

VI. Analysis of Impacts

The economic impact of the final monograph was discussed in the final rule (64 FR 27666 at 27683). This extension of the effective date provides additional time for companies to relabel, retest, and reformulate affected products and will reduce label obsolescence, as there will be additional time to use up more existing labeling. This extension will also eliminate a second relabeling of sunscreen drug products when UVA labeling is included in the monograph. Thus, extending the effective date of the final rule until December 31, 2002, and the compliance date for products with annual sales less than $25,000 to December 31, 2003, will significantly reduce the economic impact on industry.

FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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 and economic analysis 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 purpose of the final rule is to reopen the administrative record and to extend the effective date which will provide manufacturers additional time to use up existing product labeling. The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, 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.

Under the Unfunded Mandates Reform Act, FDA is not required to prepare a statement of costs and benefits for this final rule because this final rule is not expected to result in any one-year expenditure that would exceed $100 million adjusted for inflation.

The agency also certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. References

The following references are on display in Docket No. 78N–0038 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. Comment No. MM16.
2. Comment No. CP11.
3. Comment No. MM21.
4. Comment No. MM17, MM18, and MM19.
5. Comment No. PAV2.
6. Comment No. MM22.
7. Comment No. LET168.
8. Comment No. ANS6.
9. Comment No. Let170
10. Comment No. CP12.
11. Comment No. C557
12. Comment No. C111 and RPT7.
13. Letter from T. J. Donegan, The Cosmetic, Toiletry, and Fragrance Association, to J. D. Lipnicki, FDA, in OTC Vol. 06FREXT.
14. Comment No. MM14.

List of Subjects in 21 CFR Part 310

Administrative practice and procedures, Drugs, Labeling, Medical

devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

2. Section 310.545 is amended by revising paragraph (d)(31) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

* * * * *

(d) * * *

(31) December 31, 2002, for products subject to paragraph (a)(29) of this section.

Dated: May 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–14212 Filed 6–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 98N–0786]

General Hospital and Personal Use Devices; Classification of Liquid Chemical Sterilants/High Level Disinfectants and General Purpose Disinfectants

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying liquid chemical sterilants/high level disinfectants intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use into class II (special controls), and general purpose disinfectants intended to process noncritical medical devices and equipment surfaces into class I (general controls). FDA is also exempting the general purpose disinfectants from the premarket notification requirements. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA).

DATES: This rule is effective July 10, 2000.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (CDRH) (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and the FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f))) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Consistent with the act and the regulations, FDA consulted with the General Hospital and Personal Use Devices Panel (the Panel), an FDA advisory committee, regarding the classification of these devices.

The FDAMA added a new section 510(l) to the act. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Hereafter, these are referred to as ''reserved criteria.'' FDA has considered the general purpose disinfectants in accordance with the reserved criteria and determined that these devices do not require premarket notification. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.

II. Regulatory History of the Device

In the **Federal Register** of November 6, 1998 (63 FR 59917), FDA proposed to classify both liquid chemical sterilants intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use into class II and general purpose disinfectants intended to process noncritical medical devices and equipment surfaces into class I. In the same issue of the **Federal Register**, FDA proposed to exempt the general purpose disinfectants from the premarket notification requirements. FDA recognizes a ''high level disinfectant'' as a potential separate or subordinate condition of use of a sterilant and has included it in the final rule to clarify its classification status. Initially, interested persons were given until February 4, 1999, to comment on the proposed regulation. Subsequently, FDA extended the comment period to March 8, 1999, in response to an extension request.