change raises the skin dose limit for DRPs on or near the skin and for small-area (< 1.0 square centimeter) contaminations. This change makes it possible for licensees to measure or calculate skin doses for comparison to the 50-rem (0.5–Sv) limit that, when averaged over 10 square centimeters, result in dose values that more appropriately reflect the risk associated with small area exposures according to the NCRP. The increased limit in the case of DRPs will eliminate the need to frequently monitor workers for DRP contamination during work shifts for all but the highest activity DRPs, especially those having a high gamma component. This reduced monitoring will eliminate most of the whole-body dose and stochastic risk associated with monitoring to avoid exceeding the former, more restrictive skin dose limit. In addition, the relaxed skin dose limit, based on NCRP recommendations, should clarify that the consequences of transient skin contamination are less significant than the radiological and nonradiological risks that workers incur as a result of licensees' efforts to avoid skin contamination. The overly conservative use of multiple layers of protective clothing and other devices worn to prevent skin contamination cause exposure to nonradiological hazards such as heat stress, as well as a reduction in worker efficiency estimated by industry to be as much as 15 to 25 percent, which, in turn, increases whole-body dose. With the new rule licensees will be able to choose to use less protective gear at the cost of more frequent skin contamination, but with the benefit of less physical stress and reduced whole-body dose to workers.

The 1991 Federal Register Notice of final rulemaking on 10 CFR Part 20 (56 FR 23360; May 21, 1991) made it clear that the skin dose limit would be addressed in subsequent rulemaking. The Commission also said that even had the 1991 changes, primarily to dose limits, not contributed to substantial increase in occupational health and safety, such changes would also amount to a redefinition of the level of adequate protection. This change in the skin and extremity dose limit will reduce worker exposure to external dose and the associated cancer risks, and reduce worker exposure to non-radiological hazards imposed by use of overly conservative protective equipment.

In conclusion, the Commission believes that this rule change constitutes a reduction in unnecessary regulatory burden, redefines the level of adequate protection, and should substantially increase worker safety. The changes, therefore, do not require a backfit analysis under § 50.109(a)(4)(iii).

XII. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting and recording requirements, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 20.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, Sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), Secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. In § 20.1003 the definition of *Shallow-dose equivalent* (H_s is revised to read as follows:

§ 20.1003 Definitions

* * * * *

Shallow-dose equivalent (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

* * * * *

3. In § 20.1201 the introductory text of paragraph (a)(2), and paragraphs (a)(2)(ii) and (c), are revised to read as follows:

§ 20.1201 Occupational Dose Limits for Adults

(a) * * *

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

* * * * *

(ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

* * * * *

(c) The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

* * * * *

Dated at Rockville, Maryland, this 1st day of April, 2002.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 02–8246 Filed 4–4–02; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701

[Docket Nos. 98N–0337, 96N–0420, 95N–0259, and 90P–0201]

RIN 0910–AA79

Over-the-Counter Human Drugs; Labeling Requirements; Partial Delay of Compliance Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial delay of compliance dates.

SUMMARY: The Food and Drug Administration (FDA) is providing a partial delay of the compliance dates for certain products subject to its final rule that established standardized format and content requirements for the labeling of over-the-counter (OTC) drug products (Drug Facts Rule). That final rule requires all OTC drug products to comply with new format and labeling requirements within prescribed implementation periods. The agency intends in a future issue of the **Federal Register** to propose an amendment to the Drug Facts Rule to modify the labeling requirements for ''convenience-size'' OTC drug products. This final rule

postpones the compliance dates under the Drug Facts Rule for certain convenience-size OTC drug products pending the outcome of the future rulemaking.

DATES:

Effective Date: This rule is effective May 6, 2002.

Compliance Dates: For compliance dates, see section II of the **SUPPLEMENTARY INFORMATION** section of this document. Submit written comments by July 5, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

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

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized format and standardized content requirements for the labeling of OTC drug products (Drug Facts Rule). Those requirements are codified in § 201.66 (21 CFR 201.66).

Section 201.66(a) states that the content and format requirements in § 201.66 apply to the labeling of all OTC drug products. This includes products marketed under a final OTC drug monograph, products marketed under an approved new drug application (NDA) or abbreviated new drug application (ANDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), and products for which there is no final OTC drug monograph or approved NDA/ANDA.

In the Drug Facts Rule and in subsequent notices, the agency provided different dates by which OTC drug products had to comply with the new requirements. These dates varied according to the regulatory status of the products (64 FR 13254 at 13273 and 13274).

A. The Original Compliance Dates in the Drug Facts Rule

1. Products in the OTC Drug Review

When the Drug Facts Rule was issued on March 17, 1999, products marketed under final OTC drug monographs were required to comply with the final rule by April 16, 2001. Products for which a final monograph became effective on or after April 16, 1999, had to comply as of: (1) The applicable implementation date for that final monograph; (2) the next major revision to any part of the label or labeling after April 16, 2001; or (3) April 18, 2005, whichever occurred first.

Combination drug products in which all of the active ingredients were the subject of a final monograph or monographs had to comply with the Drug Facts Rule as of April 16, 2001. Combination products in which one or more active ingredients were the subject of a final monograph, and one or more ingredients were still under review as of the effective date of the final rule, had to comply as of the implementation date for the last applicable final monograph for the combination, or as of April 16, 2001, whichever occurred first. Combination products in which none of the active ingredients was the subject of a final monograph or monographs as of the effective date of the Drug Facts Rule had to comply as of: (1) The implementation date of the last applicable final monograph for the combination; (2) the next major revision to any part of the label or labeling after April 16, 2001; or (3) April 18, 2005, whichever occurred first.

2. Products Marketed Under NDAs and ANDAs

Products that were the subject of an approved drug application (NDA or ANDA) that was approved before April 16, 1999, had to comply with the Drug Facts Rule as of April 16, 2001. Products that became the subject of an approved NDA or ANDA on or after April 16, 1999, were required to comply with the Drug Facts Rule at the time of approval (64 FR 13254 at 13273).

3. Additional Provisions

In addition, any OTC drug product not described in sections I.A.1 and I.A.2 of this document had to comply with the final rule as of: (1) The next major revision to any part of the label or labeling after April 16, 2001; or (2) April 18, 2005, whichever occurred first.

Products (including combinations) marketed under a final OTC drug monograph or monographs, or under an NDA or ANDA, with annual sales of less than $25,000 had to comply with the Drug Facts Rule as of April 16, 2002. This extra time was intended to provide marketed products with a low level of distribution 1 additional year to comply with the Drug Facts Rule.

The agency provided a chart that summarized the time periods within which the various categories of marketed OTC drug products were required to comply with the Drug Facts Rule (64 FR 13254 at 13274). Unless otherwise stated, all time periods in the chart began on the effective date of the Drug Facts Rule.

B. Correction Notice

In the **Federal Register** of April 15, 1999 (64 FR 18571), the agency published a correction to the Drug Facts Rule and changed its effective date from April 16, 1999, to May 16, 1999. While the agency did not explicitly discuss the implementation plan and compliance dates for the final rule (or the chart at 64 FR 13274), the correction had the effect of changing the compliance dates for the final rule as follows: (1) The April 16, 1999, compliance date became May 16, 1999; (2) the April 16, 2001, compliance date became May 16, 2001; (3) the April 16, 2002, compliance date became May 16, 2002; and (4) the April 18, 2005, compliance date became May 16, 2005.

C. Extension of Compliance Dates

1. Citizen Petitions Requesting Additional Implementation Time

Following publication of the Drug Facts Rule and the April 15, 1999, correction, the Consumer Healthcare Products Association (CHPA) and the Cosmetic, Toiletry, and Fragrance Association (CTFA) submitted citizen petitions (Refs. 1 and 2) requesting a 2-year extension of time for compliance with the Drug Facts Rule. Both associations requested an extension of the May 16, 2001, compliance date to May 16, 2003, and the May 16, 2002, compliance date to May 16, 2004. They also urged FDA to modify the labeling requirements of the Drug Facts Rule for single-use and convenience-size packages, and the petitions requested a categorical exemption for small packages. Neither requested a change to the May 16, 2005, compliance date. CHPA also requested that FDA stay the final rule for those products that had to comply with the Drug Facts Rule immediately.

The agency answered these citizen petitions on February 4, 2000 (Refs. 3 and 4) and denied the petitioner's request for a 2-year extension of the final rule. However, the agency concluded that a 1-year delay of the May 16, 2001, compliance date to May 16, 2002 (and a corresponding delay of the May 16, 2002, compliance date for products with annual sales of less than $25,000 to May 16, 2003) was justified.

2. Notice of Delay of Compliance

In the **Federal Register** of June 20, 2000 (65 FR 38191), the agency published a final rule providing a partial extension of the compliance dates for the Drug Facts Rule, per the February 4, 2000, responses to the citizen petitions. In this final rule, the agency also restated the implementation chart that appeared in the Drug Facts Rule (64 FR 13254 at 13274), and updated it to show the new compliance dates (65 FR 38191 at 38193). In addition, the agency amended language in the chart to clarify the applicable compliance dates when relabeling was required by another rule in addition to the Drug Facts Rule. Finally, the Drug Facts Rule also required labeling revisions in 21 CFR parts 201, 330, 331, 341, 346, 355, 358, 369, and 701 (64 FR 13254 at 13291, 13292, and 13294 to 13297). The June 20, 2000, final rule delayed the May 16, 2001, and May 16, 2002, compliance dates for those revisions for 1 additional year, respectively.

II. Single-Use and Convenience-Size Packages

After FDA published its delay of compliance dates, CHPA requested a meeting to discuss class exemptions for OTC drug convenience-sizes in selected OTC categories, and it proposed several definitions of ''convenience-size'' (Ref. 5). The agency responded in a subsequent letter (Ref. 6) that CHPA's proposed definitions of ''convenience-size'' were so broad as to preclude a meaningful discussion. The agency explained that CHPA's proposed definitions of ''convenience-size'' could include many widely-used products that generally have not been (and are not) regarded as ''convenience-sizes'' (for example, packages containing 12 tablets or 4 ounces of cough/cold products, and 1-ounce tubes of topical antifungal drug products). The agency noted that adoption of an overly broad definition for ''convenience-size,'' with allowance for significant deviations from the general requirements of the rule, could circumvent the intent of the Drug Facts Rule and potentially undermine the interest of the public health and safety. The agency added that, under § 201.66(d)(10), the Drug Facts Rule already provides some flexibility in the labeling of small packages.

Thereafter, Lil' Drug Store Products, Inc., (Lil') submitted a citizen petition (Ref. 7) asking FDA to define ''convenience-size'' OTC drug products and to modify the labeling and content requirements of the Drug Facts Rule with respect to such products. Lil' proposed that ''convenience-size'' OTC drug products be defined as packages sold to the public that contain one or two doses of an OTC drug product. Lil' also proposed that ''dose'' be defined as a manufacturer's recommended serving. In addition, Lil' requested that FDA modify the requirements of § 201.66 for ''convenience-size'' OTC drug products by permitting a reduced version of OTC Drug Facts labeling to appear on the external packaging of such products, while requiring fully compliant Drug Facts labeling on the inside of the package through the use of package inserts or inner-package printing. Lil' stated that the labeling on the external packaging would: (1) Still include medically relevant information, (2) remain consistent with the retail environment in which ''convenience-size'' OTC drug products are sold, and (3) still adequately enable consumers to make the unique purchasing decision associated with their use. Lil' described its ''convenience-size'' products as recognized, brand-name, quality OTC drug products packaged in small doses and made available to the consumer at his or her point of need. Lil' also stated that these products are a low cost (they typically retail for less than $.99) alternative to traditional multidose OTC drug packages, and they are mostly marketed in convenience stores that primarily sell products with efficient-size packaging and significant brand loyalty and awareness.

In its response (Ref. 8) to the Lil' citizen petition, FDA stated that it had carefully reviewed the data and information in the petition and agreed that some accommodation for these ''convenience-size'' packages might be appropriate. However, FDA determined that additional comments from other interested persons should be considered before making a final decision, because a number of other manufacturers, repackers, and distributors would be affected by a change to the Drug Facts Rule and would likely want to comment on any proposed FDA course of action.

FDA therefore stated that it intended to prepare, for publication in a future issue of the **Federal Register**, a proposed rule that would, if finalized, amend the Drug Facts Rule by defining ''convenience-size'' OTC drug packages and addressing Drug Facts labeling requirements for such products. The proposed rule would also provide all interested parties an opportunity to comment on the viability, desirability, and impact of the proposed rule, and to respond to specific questions posed by the agency.

Accordingly, at this time, FDA is announcing a partial delay of the compliance dates for the Drug Facts Rule in § 201.66 for all OTC drug products that: (1) Contain no more than two doses of an OTC drug; and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear labeling to meet the requirements set forth in § 201.66(d)(1) to (d)(9) and therefore qualify for the labeling modifications currently set forth in § 201.66(d)(10). For purposes of this notice, ''dose'' is defined as the maximum single serving for an adult (or a child for products marketed only for children) as specified in the product's directions for use. FDA is aware that the scope of this delay may extend to some products that are also currently marketed as ''sample'' or ''trial'' sizes. FDA is amending the June 20, 2000, implementation chart to add a footnote number ''1'' next to the header ''Time Periods,'' which reads as follows:

TABLE 1.—RESTATED IMPLEMENTATION CHART

Products	Time Periods[1]
Single entity and combination products subject to drug marketing applications approved before May 16, 1999.	By May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than $25,000).
Single entity and combination products subject to drug marketing applications approved on or after May 16, 1999.	Immediately upon approval of the application.
Single entity products subject to an OTC drug monograph finalized before May 16, 1999.	By May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than $25,000).
Single entity products subject to an OTC drug monograph finalized on or after May 16, 1999.	Within the period specified in the final monograph. However, if a monograph has not been finalized as of May 16, 2002, then the product must comply as of the first major labeling revision after May 16, 2002, or by May 16, 2005, whichever occurs first.

TABLE 1.—RESTATED IMPLEMENTATION CHART—Continued

Products	Time Periods[1]
Combination products subject to an OTC drug monograph or monographs in which all applicable monographs were finalized before May 16, 1999.	By May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than $25,000).
Combination products subject to an OTC drug monograph or monographs in which at least one applicable monograph was finalized before May 16, 1999, and at least one applicable monograph is finalized on or after May 16, 1999.	Within the period specified in the last applicable monograph to be finalized, or by May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than $25,000), whichever occurs first, unless the last applicable monograph to be finalized specifies a later date.
Combination products subject to an OTC drug monograph or monographs in which all applicable monographs are finalized on or after May 16, 1999.	Within the period specified in the last applicable monograph to be finalized. However, if the last monograph is not finalized as of May 16, 2002, then the product must comply as of the first major labeling revision after May 16, 2002, or by May 16, 2005, whichever occurs first.
All other single entity and combination OTC drug products (e.g., products in the OTC drug review that are not yet the subject of proposed OTC drug monographs).	If a monograph has not been finalized as of May 16, 2002, then the product must comply as of the first major labeling revision after May 16, 2002, or by May 16, 2005, whichever occurs first.

[1] Time delayed until further notice for OTC drug products that contain no more than two doses of an OTC drug product and, because of their limited total surface area available to bear labeling, qualify for the labeling modifications set forth in § 201.66(d)(10).

FDA based the scope of this delay on Lil's petition, which defined ''convenience-size'' as a product containing one or two doses of an OTC drug. Since the petition did not explicitly address the issue of package size, FDA decided to adopt the threshold set forth in § 201.66(d)(10), because it is the one section of the current Drug Facts Rule that differentiates OTC drug packages based on size. The agency believes that the scope of this delay reflects the current marketplace in that the delay includes most, if not all, OTC drug products that are currently sold as ''convenience-size.''

The delay in the compliance dates for the OTC drug packages described in this notice will remain in effect until a final rule issues with respect to the labeling of such OTC drug products or until such time as the agency issues further notice. In either case, the delay enables manufacturers of the packages described in this notice to continue marketing those products in their present labeling formats pending resolution of this issue. The labeling of such packages still needs to comply with the act and all other applicable regulatory requirements. Notwithstanding this delay in compliance dates, manufacturers who wish to do so may still relabel the affected products in the Drug Facts format, particularly when existing labeling is exhausted and relabeling would occur in the normal course of business, using any of the alternative design techniques described in the final rule (64 FR 13254 at 13268).

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C 553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to the public interest. The agency is delaying the compliance date of § 201.66 for products that meet the specific criteria described in this notice because the agency intends to publish a proposal to amend § 201.66 by defining ''convenience-size'' drug packages and addressing Drug Facts labeling requirements for such packages. There will be an opportunity to comment on the new compliance date for such products within the proposed amendment to § 201.66. In addition, given the imminence of the current compliance dates, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that the agency would be proposing to extend the compliance date for § 201.66, those companies affected would have to be preparing to relabel to comply with the May 16, 2002, compliance date. In accordance with 21 CFR 10.40(e)(1), FDA is also providing an opportunity for comment on whether this delay should be modified or revoked.

III. Analysis of Impacts

The economic impact of the Drug Facts Rule was discussed in the final rule (64 FR 13254 at 13276 to 13285). This partial delay of the compliance dates provides additional time for companies to relabel certain products to comply with the final rule. CHPA, in its request for a meeting (Ref. 5), stated that ''convenience-sizes'' represent less than 1 percent of the retail market. The partial delay for the products described in this notice will also reduce label obsolescence as companies will have additional time to use up more existing labeling. Thus, delaying the compliance dates for implementation for these specific products will significantly reduce the economic impact of the final rule on manufacturers of these products.

FDA has examined the impacts of this final rule (partial delay of the compliance dates) 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 of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency concludes that this final rule is consistent with the principles set out in the Executive order and in these two statutes. This 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. As discussed in this section, FDA has determined that this final rule will not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million.

The purpose of this final rule is to provide a partial delay of the compliance dates by which manufacturers need to relabel their ''convenience-size'' products, as defined in this final rule. Accordingly, under the Regulatory Flexibility Act, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

IV. The Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. 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.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. References

The following references are 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. Comment No. CP2, Docket No. 98N–0337.

2. Comment No. CP1, Docket No. 99P–4617.

3. Letter from W. K. Hubbard, FDA, to B. N. Kuhlik and M. S. Labson, Covington & Burling, coded PAV2, Docket No. 98N–0337.

4. Letter from W. K. Hubbard, FDA, to E. E. Kavanaugh, CTFA, coded PAV1, Docket No. 99P–4617.

5. Letter from R. W. Soller, CHPA, to C. Ganley, FDA, dated October 3, 2000, Docket No. 98N–0337.

6. Letter from C. Ganley, FDA, to R. W. Soller, CHPA, dated December 22, 2000, Docket No. 98N–0337.

7. Comment No. CP1, Docket No. 01P–0207.

8. Letter from S. Galson, FDA, to J. M. Nikrant, Lil' Drug Store Products, Inc., coded LET 1, Docket No. 01P–0207.

VIII. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this final rule by July 5, 2002. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This final rule (partial delay of compliance dates) is issued under sections 201, 501, 502, 503, 505, 510, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, and 371) and under authority of the Commissioner of Food and Drugs.

Dated: March 23, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8193 Filed 4–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Chapter V

Addition of Persons to Appendix A to 31 CFR Chapter V

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Amendment of final rule.

SUMMARY: The Treasury Department is amending appendix A to 31 CFR chapter V to add the names of two organizations designated as persons whose property and interests in property have been blocked under the authority of the Secretary of the Treasury pursuant to Section 1(a)(ii) of Executive Order 13219 of June 26, 2001.

EFFECTIVE DATE: April 2, 2002.

FOR FURTHER INFORMATION CONTACT: Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: 202/622–2520.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

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Background

Appendix A to 31 CFR chapter V lists the names of blocked persons, specially designated nationals, specially designated terrorists, foreign terrorist organizations, and specially designated narcotics traffickers with respect to whom transactions are subject to the various economic sanctions programs administered by the Treasury Department's Office of Foreign Assets Control (''OFAC'').

On June 26, 2001, President Bush issued Executive Order 13219 (66 FR 34777, June 29, 2001), imposing economic sanctions on persons who threaten international stabilization efforts in the Western Balkans region. In an annex to the order, President Bush identified twenty-three individuals and five organizations with respect to which transactions are subject to those sanctions. Those individuals and organizations have already been incorporated into appendix A as blocked persons identified by the term ''[Balkans]'' (66 FR 57371, November 15, 2001).

On November 28, 2001, the Albanian National Army (ANA) (a.k.a. AKSH) and the National Committee for the