Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 1998N–0583]

Exports; Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is considering whether to revise its regulations pertaining to export notification and recordkeeping. FDA has received a petition for reconsideration claiming that the agency lacks legal authority to inspect export records held by food and cosmetic companies. The petition also claimed that the regulations describing the types of records that should be kept to demonstrate that an exported product does not conflict with the foreign country's laws are overly burdensome. FDA is inviting comment on the issues raised by the petition.

DATES: Submit written or electronic comments by August 16, 2004.

ADDRESSES: You may submit comments, identified by Docket No. 1998N–0583, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include Docket No. 1998N–0583 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see section IV of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of December 19, 2001 (66 FR 65429), we published a final rule to establish notification and recordkeeping requirements for products exported under section 801(e) or 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e) or 382), as amended by the FDA Export Reform and Enhancement Act (Public Law 104–134, as amended by Public Law 104–180).

The FDA Export Reform and Enhancement Act significantly changed and simplified the export requirements for unapproved human drugs, biological products, devices, and animal drugs. For example, before the law was enacted, most exports of unapproved new drug products could only be made to the 21 countries then identified in section 802 of the act, and these exports were subject to numerous restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new human drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA) and certain other requirements are met (see section 802(b)(1)(A) of the act). Currently, the EU countries are Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. (The list of countries under section 802(b)(1)(A) of the act will expand automatically if any country accedes to the EU or becomes a member of the EEA.) This provision of section 802 of the act also applies to the export of certain devices that cannot be sold or marketed in the United States.

The FDA Export Reform and Enhancement Act also established recordkeeping and notification requirements. Section 802(g) of the act requires an exporter of a drug or device under section 802(b)(1)(A) of the act to provide a ''simple notification'' to the agency ''identifying the drug or device when the exporter first begins to export such drug or device'' to any of the countries identified in section 802(b)(1)(A). For exports to other, nonlisted countries, section 802(g) of the act requires the exporter to provide a simple notification ''identifying the drug or device and the country to which such drug or device is being exported.'' This section also requires persons exporting under any provision of section 802 of the act to ''maintain records of all drugs or devices exported and the countries to which they were exported.''

The final rule was originally scheduled to become effective on March 19, 2002. However, within days of the effective date, four different parties (the law firm of Sandler, Travis and Rosenberg; the Consumer Healthcare Products Association; INDA; and the Cosmetic, Toiletry, and Fragrance Association) requested a 180-day stay in the rule's effective date. In general, the parties acknowledged that they had not submitted comments during the rulemaking process, but stated that they did not realize the rule's applicability to their products. Consequently, the parties claimed they needed additional time to comply with the final rule, and they raised other questions regarding the rule. In response, on March 18, 2002, we notified the parties that we would stay the rule's effective date for

90 days, and we published a notice in the **Federal Register** on May 14, 2002 (67 FR 34387), announcing that the rule's new effective date was June 19, 2002. We also issued separate letters responding to the parties' questions on May 7, 2002.

On June 17, 2002, 2 days before the final rule was to become effective, the law firm of Covington and Burling, on behalf of the Grocery Manufacturers of America and the Cosmetic, Toiletry, and Fragrance Association, submitted a petition for reconsideration and stay of action. The petition challenged two specific provisions in the final rule.

The first provision involved the last sentence in § 1.101(b) (21 CFR 1.101(b)), which states that export records must be made available to FDA upon request during an inspection for review and copying. We included such records access in the final rule because most exports under sections 801(e)(1) and 802 of the act do not involve any prior FDA oversight. Therefore, we depend on records access during inspections to evaluate compliance with the export provisions. In the preamble to the final rule, we explained that records enable a person to show, and for us to verify, that a person has complied with its legal obligations. Nevertheless, the firm asserted that we lack the authority to require food or cosmetic companies to disclose records because our inspection authority does not extend to the mandatory examination of records maintained by food and cosmetic manufacturers, and asked us to revoke the sentence in § 1.101(b) as it pertains to access to food and cosmetic records.

The second provision involved § 1.101(b)(2) which describes the records that could be used to demonstrate that an exported product does not conflict with a foreign country's laws. Section 801(e)(1)(B) of the act requires exported products to not be in conflict with ''the laws of the country to which it is intended for export.'' In the preamble to the proposed rule (April 2, 1999, 64 FR 15994), we stated that the records demonstrating compliance with section 801(e)(1)(B) of the act would normally consist of a letter from the appropriate foreign government agency, department, or other authorized body. We received many comments that opposed our interpretation, and so, in response to the comments, we revised the final rule to state that the records:

> may consist of either a letter from an appropriate foreign government agency, department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws, or a notarized certification by a responsible company official in the United States that the product does not conflict with the laws of the importing country and that includes a statement acknowledging that he or she is subject to the provisions of 18 U.S.C. 1001.

The preamble to the final rule did not specify who would be a ''responsible company official in the United States,'' but it did explain that 18 U.S.C. 1001 makes it a criminal offense to knowingly and willfully make a false or fraudulent statement, or make or use a false document, in any matter within the jurisdiction of a department or agency of the United States (see 66 FR 65429 at 65436).

The petition for reconsideration, however, asserted that exporters do not have to demonstrate compliance with foreign law; instead, it asserted that FDA had the burden to show that the exporter violated foreign law. The petition added that § 1.101(b)(2) would, if enforced, have ''serious practical and economic impacts on food and cosmetic companies'' because it would ''require the preparation of tens of thousands of affidavits just for shipping products to our neighbors in Mexico * * * and Canada * * *, and new affidavits would be required for every product variation and every label change'' (Ref. 1). Later, after meeting with FDA, the petitioners stated in correspondence to the agency that ''there can be no objection from a policy standpoint to a general requirement that every company must have adequate documentation in its files to support its conclusion that the product does not violate the laws of the foreign country to which it is exported'' (Ref. 2). The firm continued to advocate eliminating ''the need for an affidavit by a high-ranking company official,'' but suggested ''the possibility of continuing the requirement of an affidavit in the unique and limited situation where FDA has established a specific requirement for a food or cosmetic in order to prevent a serious health hazard and the product to be exported does not meet that requirement'' (id.). The firm explained that the ''affidavit'' requirement would arise in two instances:

> The first instance would be where FDA has established a label warning for a product. An example would be the warning for aspartame in 21 CFR 172.804. The second instance would be where FDA has established a specific limit on the presence of an ingredient or substance because of substantial safety concerns. Examples would be Compliance Policy Guides 555.300 for salmonella and 555.400 for afflatoxin [sic] in food and the limit on mercury in cosmetics in 21 CFR 700.13. This would not, however, include the limits customarily established in food additive, GRAS, and color additive regulations because these are set simply at the level requested by the manufacturer and are not because of a specific determination by FDA that any higher limit is a serious health hazard. It also would not apply to a food ingredient or a color ingredient which FDA has not reviewed and therefore has taken no action. It is common industry practice to manufacture products in the United States that contain ingredients or levels of ingredients approved or permitted by foreign countries but not by FDA. If affidavits were required for all of these types of situations, it would simply drive food and cosmetic manufacturers abroad.

Id. at pages 1-2.

In response to the petition for reconsideration, we decided to exercise enforcement discretion regarding access to records of food and cosmetic exporters under § 1.101(b) and to exercise enforcement discretion regarding all exporters and the requirement for specific types of records under § 1.101(b)(2) demonstrating that the exported product is not in conflict with the foreign country's laws (Ref. 3). We stated that affected parties must still comply with the statutory requirements pertaining to exports, and added that we would evaluate whether to issue an advance notice of proposed rulemaking ''to obtain public comment on questions related to the issues raised in your petition'' (id. at page 2).

II. Issues For Discussion

We invite comment on the following issues.

1. *What is our ability to inspect export records held by food and cosmetic firms?*

The petition for reconsideration asserted that we lack legal authority to inspect records related to food and cosmetic exports. Given that food and cosmetic exports under section 801(e)(1) of the act do not require any prior FDA review or even notice to FDA before a firm exports a food or cosmetic, it could be extremely difficult for us to determine a food or cosmetic company's compliance with the act's export provisions if we could not inspect export records. Without access to such records, our enforcement of section 801(e)(1) of the act would likely depend on information submitted voluntarily to us, and it is hard to rely on a company to provide information about itself that would indicate a possible violation of Federal law. It also would be unlikely that third parties would have or provide information showing that a food or cosmetic firm failed to meet the act's export requirements. At best, outside parties might be able to provide information to suggest a failure to comply, but we would still need additional information before pursuing regulatory action.

Additionally, if we could not inspect export records in a food or cosmetic company, then an unscrupulous food or cosmetic firm might be tempted to not comply with the export requirements at all because it would know that, without access to export records, our ability to evaluate compliance with those export requirements would be severely limited. Noncompliance with export requirements could expose populations in foreign countries to unsafe products.

Complicating our situation further is the fact that section 801(d)(3) of the act allows certain unapproved or otherwise noncompliant articles to be imported into the United States as long as those articles are further processed or incorporated into a product that is then exported. Section 801(d)(3) of the act is commonly known as the ''import for export'' authority in the act, and it applies to food additives, color additives, and dietary supplements. Section 801(d)(3)(A)(iv) of the act expressly requires the initial owner or consignee to maintain ''records on the use or destruction'' of the imported article and to submit to the Secretary of Health and Human Services (the Secretary) ''any such records requested by the Secretary.'' Thus, if a food company imported a food additive under section 801(d)(3) of the act, section 801(d)(3)(A)(iv) requires the food company to maintain certain records, including those pertaining to any exports involving the article, and also requires the food company to submit ''any such records.'' Accordingly, the petitioners' request to revoke § 1.101(b), as it relates to access to food records, is in tension with section 801(d)(3)(A)(iv) of the act.

Consequently, we seek comment on:

• Our ability to access or inspect food and cosmetic export records; and

• Whether we need to provide alternative methods for determining whether a food or cosmetic firm has complied with the act's export requirements. For example, one might argue that a certification should be satisfactory, but a certification would be contrary to the petitioners' claim that ''affidavits'' are burdensome.

2. *What records should an exporter have to show that the export does not conflict with the foreign country's laws?*

Although § 1.101(b)(2) states that the records demonstrating that the export does not conflict with the foreign country's laws ''may'' consist of either a letter from the appropriate foreign government entity or a certification from a ''responsible company official'' in the United States, the petitioners apparently interpret § 1.101(b)(2) as requiring the record to be either a letter from a foreign government entity or a certification from a ''high-ranking company official'' (Ref. 2). In other words, the petitioners appear to interpret the word ''may'' in § 1.101(b)(2) as ''must.''

Therefore, we invite comment on the following issues:

• Should FDA amend the rule?

• Does the word ''may'' provide sufficient flexibility to give affected parties the ability to keep whatever records they wish to demonstrate that the export does not conflict with the foreign country's laws?

• Given that the petitioners focused on the certification, would a clarification that the ''responsible company official'' does not necessarily mean a ''high-ranking company official'' be sufficient? For example, if a company's regulatory affairs director determined that the export did not conflict with the foreign country's laws, the regulatory affairs director could provide the certification (unless company policy dictated a different result). We do not necessarily equate ''responsible'' with ''high-ranking.''

• What are the advantages and disadvantages in the petitioners' suggestion of a certification in some, but not all, food export situations? The petitioners identified two scenarios in which such certifications would be provided: Cases where FDA has established a label warning for a product and cases where FDA has established a specific limit on the presence of an ingredient or substance because of substantial safety concerns. The petitioners' suggestion thus depends on the existence of a regulation that imposes a label warning or that limits an ingredient's or substance's use due to ''substantial safety concerns.'' However, the petitioners' suggestion would exclude customary limits established in food additive, generally recognized as safe, and color additive regulations, so few food exports would need a certification. While the petitioners' suggestion would free most food exports from the certification provision, we are concerned that it might not provide sufficient guidance on what records would be acceptable to show that the export did not conflict with the foreign country's laws. Moreover, when coupled with the petitioners' assertion that we have no authority to inspect food records, could the petitioners' position eliminate our ability to determine whether a food export complied with a foreign country's laws?

• Is there another alternative that would be simple and reliable? Ideally, the alternative would meet most, if not all, of the following conditions for a regulatory requirement:

• A consistent regulatory standard for all firms affected by or subject to the same statutory requirement. A consistent standard would be easier for our investigators to apply and easier to implement by firms that export more than one type of product that would be subject to section 801(e)(1) of the act.

• A record that provides a reasonable basis for the exporter's belief that the export does not conflict with the foreign country's laws. For example, a statement such as, ''To the best of my knowledge, the export did not conflict with the foreign country's laws,'' may be unreliable because the phrase, ''to the best of my knowledge'' does not mean that the exporter knows about or even attempted to know about the foreign country's laws. Similarly, a statement claiming that someone in the foreign country affirmed that the export did not conflict with the foreign country's laws may be unreliable because the foreign citizen making the statement might not have been qualified to determine whether the export did not conflict with the foreign country's laws.

• A record that is simple and easy to identify. We conduct inspections to determine whether a firm complied with the appropriate export requirements, so the inspection would be shorter and easier if all parties could agree on the types of records that would demonstrate compliance with a particular regulatory requirement.

• A record that permits enforcement action in the United States. When we stated that the certification had to be from a responsible company official in the United States, the official's physical presence in the United States would give us the ability to pursue enforcement action against the official if the certification proved to be false or misleading. In contrast, if the record was created by an unknown foreign citizen in a foreign country, we might find it difficult to take action against the foreign citizen, and our ability to enforce the statute could be compromised.

III. References

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

1. Petition for Reconsideration and Stay of Action, Covington and Burling, pp. 2 and 3, June 17, 2002.

2. Letter from Peter Barton Hutt, Covington and Burling, to Daniel E. Troy, General

Counsel, Food and Drug Administration, p. 1, dated July 16, 2002.

3. Letter from Margaret M. Dotzel, Associate Commissioner for Policy, Food and Drug Adminstration, to Peter Barton Hutt, Covington and Burling, July 22, 2002.

IV. Request For Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This ANPRM is issued under section 201 et al. of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et al.) and under authority of the Commissioner of Food and Drugs.

Dated: April 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12271 Filed 5–28–04; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA250–0453; FRL–7668–3]

Disapproval of State Implementation Plan Revisions, Monterey Bay Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to disapprove a revision to the Monterey Bay Unified Air Pollution Control District (MBUAPCD) portion of the California State Implementation Plan (SIP) concerning excess emissions during breakdown. We are proposing action on a local rule that regulates these emissions under the Clean Air Act as amended in 1990 (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by July 1, 2004.

ADDRESSES: Send comments to Andrew Steckel, Rulemaking Office Chief (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105 or e-mail to *steckel.andrew@epa.gov*, or submit comments at *http://www.regulations.gov*.

You can inspect copies of the submitted rule revisions, EPA's technical support document (TSD), and public comments at our Region IX office during normal business hours by appointment. You may also see copies of the submitted rule revisions by appointment at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 ''I'' Street, Sacramento, CA 95814.

Monterey Bay Unified Air Pollution Control District, 24580 Silver Cloud Court, Monterey, CA 93940.

A copy of the rule may also be available via the Internet at *http://www.arb.ca.gov/drdb/drdbltxt.htm*. Please be advised that this is not an EPA Web site and may not contain the same version of the rule that was submitted to EPA.

FOR FURTHER INFORMATION CONTACT: Thomas C. Canaday, EPA Region IX, (415) 947–4121, *canaday.tom@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to EPA.

Table of Contents

I. The State's Submittal

A. What Rule Did the State Submit?

Table 1 lists the rule proposed for disapproval with the date that it was adopted and submitted by the California Air Resources Board (CARB).

TABLE 1.—SUBMITTED RULE

Local agency	Rule No.	Rule title	Adopted	Submitted
MBUAPCD	214	Breakdown Condition	03/21/01	10/30/01

On January 18, 2002, we determined that the rule submittal in Table 1 met the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.

B. Are There Other Versions of This Rule?

We approved a version of MBUAPCD Rule 214 into the SIP on July 13, 1987.

C. What Are the Changes in the Submitted Rule?

Rule 214 establishes that MBUAPCD may elect to take no enforcement action against an owner or operator of any equipment which has violated an emission standard or operational requirement provided that a breakdown has occurred and certain other conditions are met. The submitted revisions to MBUAPCD Rule 214 modify the rule's format and add clarifying language. The TSD has more information about this rule.

II. EPA's Evaluation and Action

A. How Is EPA Evaluating the Rule?

Generally, SIP rules must be enforceable (see section 110(a) of the Act), must require Reasonably Available Control Technology (RACT) for major sources in nonattainment areas (see section 182(a)(2)(A)), and must not relax existing requirements (*see* sections 110(l) and 193).

Guidance and policy documents that we used to help evaluate specific enforceability requirements consistently include the following:

1. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook).

2. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).

3. ''State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup and Shutdown,'' EPA Office of Air and