

Capacity	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Compact:		
Top Loading .....	607	1,226
Front Loading .....	( <sup>1</sup> )	( <sup>1</sup> )
Standard:		
Top Loading .....	603	1,818
Front Loading .....	306	395

<sup>1</sup>No data submitted.

By direction of the Commission.

**Benjamin I. Berman,**  
Acting Secretary.

[FR Doc. 95-9930 Filed 4-20-95; 8:45 am]

BILLING CODE 6750-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 206**

[Docket Nos. 88P-0380 and 89P-0163]

**Imprinting of Solid Oral Dosage Form Drug Products for Human Use; Clarification**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; clarification.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations requiring the imprinting of solid oral dosage form drug products for human use. This final rule clarifies FDA's intent regarding the effective date for drug products introduced or delivered for introduction into interstate commerce.

**DATES:** Effective September 13, 1995; written comments by July 20, 1995.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Deborah A. Wolf, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1046.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of September 13, 1993 (58 FR 47948), FDA published a final rule requiring the imprinting of all solid oral dosage form drug products for human use. The regulation requires that all drugs covered by it bear an

imprint that will permit the identification of the drug product, including its active ingredients and dosage strength, and its manufacturer or distributor. The regulation was based on a proposed rule that was published in the **Federal Register** of May 15, 1991 (56 FR 22370). The preamble to the proposed rule stated that, among other things, any final rule based on the proposal would become effective 1 year after its date of publication in the **Federal Register**. The preamble also stated that any drug product subject to the requirements of this rule that is "introduced or delivered for introduction into interstate commerce" after the effective date would be deemed to be adulterated, misbranded, or an unapproved new drug, unless it is imprinted in compliance with the regulation (see 56 FR 22370 at 22375 (emphasis added)). Under the proposed rule, FDA intended the rule to be effective for drug products entering interstate commerce at the manufacturing level 1 year after the date of publication of a final rule in the **Federal Register**.

In response to the proposed rule, many drug companies commented that 1 year was insufficient time to comply with the requirements of the rule. Industry comments indicated that it would take longer than 1 year for equipment retooling and product imprinting.

In response to industry's concerns, FDA provided for an implementation period of 2 years. The agency intended to provide an effective date of September 13, 1995, which is 2 years after its date of publication in the **Federal Register**.

However, in revising the final rule to provide for a 2-year implementation period, the agency inadvertently replaced the reference to drug products "introduced or delivered for introduction into interstate commerce" with a reference to drug products "distributed in interstate commerce" (see 58 FR 47948 at 47950) (emphasis added). This change created the misimpression that FDA intended the rule to apply to drug products distributed by manufacturers, repackers, and retail distributors, thereby increasing, rather than decreasing, the burden on the pharmaceutical industry. FDA has received inquires expressing concern that FDA intended to initiate recall actions at the retail level because "distribution" would include sale at that level.

This final rule amends 21 CFR 206.10(a) by replacing the language "distributed in interstate commerce" with "introduced or delivered for

introduction into interstate commerce." This will clarify the requirements of the rule as it pertains to products in interstate commerce.

Because this amendment to the imprinting regulations makes only a change necessary to conform the rule to FDA's original intention as stated in the preamble to the proposed rule and to be consistent with the agency's intent to provide a 2-year implementation period as provided for in the final rule, notice and public procedure are unnecessary. FDA finds that there is good cause to dispense with notice of proposed rulemaking, pursuant to 5 U.S.C. 553(b)(3)(B). FDA is therefore publishing this revision as a final rule effective September 13, 1995. However, the agency is giving interested persons 90 days to comment on this final rule.

**II. Request for Comments**

Interested persons may, on or before July 20, 1995, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 206**

Drugs.

**PART 206—IMPRINTING OF SOLID ORAL DOSAGE FORM DRUG PRODUCTS FOR HUMAN USE**

1. The authority citation for 21 CFR part 206 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 355, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

2. Section 206.10 is amended by revising the first sentence of paragraph (a) to read as follows:

**§ 206.10 Code imprint required.**

(a) Unless exempted under § 206.7, no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product. \* \* \*

\* \* \* \* \*

Dated: April 13, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95-9951 Filed 4-20-95; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Office of Justice Programs

#### Office of Juvenile Justice and Delinquency Prevention

#### 28 CFR Part 31

[OJP No. 1045]

RIN 1121-AA28

#### Formula Grants; Correction

Date: April 13, 1995.

**AGENCY:** Department of Justice, Office of Justice Programs, Office of Juvenile Justice and Delinquency Prevention.

**ACTION:** Correction to final regulation.

**SUMMARY:** This document contains corrections to the Final Regulation, revising 28 CFR part 31, which was published in the **Federal Register** on Friday, March 10, 1995, (60 FR 13330). The regulation revisions provided clarification and guidance to States in the formulation, submission and implementation of the State Formula Grants Program under Part B of Title II of the Juvenile Justice and Delinquency Act of 1974, as amended by the Juvenile Justice and Delinquency Prevention Amendments of 1992 (Pub. L. 102-586, November 18, 1992).

The 1992 Amendments reauthorize and modify the Federal assistance program to State, local governments, and private not-for-profit agencies for the prevention and control of delinquency and improvement of the juvenile justice system. This final revision to the existing regulation provides clarification and guidance to States in the formulation, submission, and implementation of State Formula Grants Program plans and determinations of State compliance with plan requirements. It provides additional flexibility and guidance to participating States while strengthening several key provisions related to the deinstitutionalization, separation, jail and lockup removal, and disproportionate minority confinement plan requirements of the JJDP Act. **EFFECTIVE DATE:** This regulation is effective March 10, 1995.

**FOR FURTHER INFORMATION CONTACT:** Roberta Dorn, Director, State Relations and Assistance Division, Office of Juvenile Justice and Delinquency

Prevention (OJJDP), 633 Indiana Avenue NW., Room 543, Washington, D.C. 20531; (202) 307-5924.

**SUPPLEMENTARY INFORMATION:** The corrections include the requirement that collocated juvenile detention facilities approved by the State and concurred with by OJJDP on or before June 30, 1995, be reviewed against the regulatory criteria and OJJDP policies in effect at the time of the initial approval and concurrence. Facilities approved after the effective date of this regulation and prior to July 1, 1995, will be reviewed against the regulatory criteria in effect on the day before the effective date of this regulation. For those collocated juvenile detention facilities considered after June 30, 1995, OJJDP's concurrence is limited to one year and, thereafter, will be reviewed on an annual basis. The requirement that in order to receive OJJDP's initial and subsequent concurrences, a collocated juvenile detention facility must only provide secure custody for juvenile criminal-type offenders, status offenders accused of violating a valid court order, and adjudicated delinquents and valid court order violators who are awaiting disposition hearings or transfer to a long term juvenile correctional facility, has been eliminated.

#### Need for Correction

As published in the **Federal Register** on March 10, 1995, (60 FR 13330), the Final Regulation was an earlier draft version that is materially different from the final draft that was intended to be published. These errors are in need of correction.

#### Correction of Publication

Accordingly, the Final Regulation, as published in the **Federal Register** on March 10, 1995, which was the subject of FR Doc. 95-5919, is corrected as follows:

#### § 31.301 [Corrected]

**Paragraph 1.** On page 13334 in amendatory instruction 6, paragraph (e) of § 31.301 was revised. Paragraph (e) of § 31.301 in the second column, line 30, the numerals "1994" are corrected to read "1995".

#### § 31.302 [Corrected]

**Paragraph 2.** On page 13334 in amendatory instruction 7, paragraph (b)(2) of § 31.302 was revised. Paragraph (b)(2) of § 31.302 is corrected to read as follows:

\* \* \* \* \*

(b) \* \* \*

(2) Should consider in meeting the statutory membership requirements and responsibilities of section 223(a)(3) (A)-

(E), appointing at least one member who represents each of the following: A locally elected official representing general purpose local government; a law enforcement officer; representatives of juvenile justice agencies, including a juvenile or family court judge, a probation officer, a prosecutor, and a person who routinely provides legal representation to youth in juvenile court; a public agency representative concerned with delinquency prevention and treatment; a representative from a private, non-profit organization, such as a parents group, concerned with teenage drug and alcohol abuse; a high school principal; a recreation director; a volunteer who works with delinquent or at risk youth; a person with a special focus on the family; a youth worker experienced with programs that offer alternatives to incarceration; persons with special competence in addressing problems of school violence and vandalism and alternatives to expulsion and suspension; and persons with knowledge concerning learning disabilities, child abuse and neglect, and youth violence.

\* \* \* \* \*

#### § 31.303 [Corrected]

**Paragraph 3.** On page 13335, in the second column, in amendatory instruction 11, paragraph (d)(l)(i) of § 31.303 was revised. Paragraph (d)(1)(i) of § 31.303, line ten, the word "no" is corrected to read "any".

**Paragraph 4.** On page 13335 in amendatory instruction 13, paragraph (e)(3) of § 31.303 was revised. Paragraph (e)(3) of § 31.303 is corrected by removing (e)(3)(v). As corrected, § 31.303(e)(3) reads as follows:

\* \* \* \* \*

(e) \* \* \*

(3) *Collocated facilities.* (i) Determine whether or not a facility in which juveniles are detained or confined is an adult jail or lockup. The JJDP Act prohibits the secure custody of juveniles in adult jails and lockups, except as otherwise provided under the Act and implementing OJJDP regulations. Juvenile facilities collocated with these adult facilities are considered adult jails or lockups unless the paragraph (e)(3)(i)(D) (1)-(4) criteria established in this section are complied with and the determinations and concurrences set forth in paragraph (e)(3) (ii), (iii), and (iv) of this section have been made.

(A) A collocated facility is a juvenile facility that is located in the same building as is located in the same building as an adult jail or lockup, or is part of a related complex of buildings located on the same grounds as an adult jail or lockup. A complex of buildings