(1) A person seeking a determination for purposes of Subpart C of Part 271 that an additional well on an existing statutorily-established proration unit in Oklahoma, for which an increased density order containing a finding of necessity has been issued, is a new, onshore production well, shall file with the Oklahoma jurisdictional agency an application which contains in lieu of the information specified in § 274.204, the following items:

(i) FERC Form No. 121;

(ii) The well completion report;

(iii) A location plat which locates and identifies the State law proration unit (as defined in § 271.305(a)(2)) and the well for which a determination is sought and all other wells within the State law proration unit in which the well for which a determination is sought is located;

(iv) A statement by the applicant, under oath;

(A) That the surface drilling of the well for which he seeks a determination was begun on or after February 19, 1977:

(B) that the well satisfies any applicable Federal or State well spacing requirements;

(C) that the applicant has concluded that to the best of his information, knowledge and belief, the natural gas for which he seeks a determination is produced from a new, onshore production well; and

(D) that the applicant has no knowledge of any other information not described in the application which is inconsistent with his conclusion;

(v) If the jurisdictional agency so requires, certified copies of records relied on by the applicant including copies of the agency's official files; and

(vi) A copy of the increased density order issued by the Oklahoma Corporation Commission which contains the finding of necessity for additional wells in the proration unit in which the well for which the determination is being sought is located.

(2) With respect to wells to which this paragraph applies, receipt by the Commission of a notice of determination pursuant to § 274.104 shall be deemed to satisfy:

(i) The requirement of notice to the Commission under § 271.305(c), and

(ii) The requirement of § 271.305(b)(1) that appropriate geological and engineering data be included in the notice of determination.

[FR Doc. 81–19788 Filed 7–6–81; 8:45 am]

BILLING CODE 6450–85–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 103, 152, 175

[T.D. 81-168]

Customs Regulations Relating To Availability of Information; Correction

AGENCY: U.S. Customs Service, Treasury.

ACTION: Final rule; correction.

SUMMARY: This document corrects the text of a final rule on the Customs Regulations relating to the availability of information that was published as T.D. 81–168 in the **Federal Register** on June 24, 1981 (46 FR 32564).

FOR FURTHER INFORMATION CONTACT: Steven I. Pinter, Disclosure Law Branch (202–566–8681).

The following corrections are made in the final rule document:

1. On page 32566, center column, the address of public reading room in Region V-New Orleans, is corrected to read "Room 302, 423 Canal Street, New Orleans, Louisiana 70130."

§103.5 [Corrected]

2. On page 32567, right-hand column, § 103.5(b)(1), the name "Freedom of Information and Privacy Branch" is corrected to read "Disclosure Law Branch."

§103.8 [Corrected]

3. On page 32570, left-hand column, section 103.8(a)(3) is corrected to read "The need for consultation, * * *, or within offices of the United States Customs Service * * *"

Dated: June 30, 1981.

B. J. Fritz,

Director, Regulations Control and Disclosure Law Division.

[FR Doc. 81–19898 Filed 7–8–81; 8:45 am]

BILLING CODE 4810–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 50

[Docket No. 78N–0049]

Protection of Human Subjects; Prisoners Used as Subjects in Research; Change of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; change of effective date.

SUMMARY: The Food and Drug Administration (FDA) is changing the effective date for §§ 50.1 and 50.3(b) (21 CFR 50.1 and 50.3(b)) which was inadvertently deferred in a notice published in the **Federal Register** of March 27, 1981 (46 FR 18951).

DATE: Sections 50.1 and 50.3(b) will become effective July 27, 1981.

FOR FURTHER INFORMATION CONTACT: Halyna P. Breslawec, Office of Health Affairs (HFY–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 27, 1981 (46 FR 18951), FDA issued a notice to delay the scheduled effective date of the final rule establishing certain provisions of 21 CFR Part 50. (See 45 FR 36386; May 30, 1980.)

The March 27, 1981 **Federal Register** notice was inadvertently drafted too broadly. It was intended to defer only the effective date of the provisions of the May 30, 1980 find rule concerning research on prisoners. The May 30 rule, however, included two introductory sections to FDA's general regulations on protection of human subjects (21 CFR Part 50). The effective date of these two sections, § 50.1 (establishing the scope of Part 50) and § 50.3(b) (defining "application for research or marketing permit"), was unintentionally deferred in the March 27, 1981 notice. By this notice, FDA advises that §§ 50.1 and 50.3(b) will go into effect on July 27, 1981, with the remainder of FDA's general regulations on protection of human subjects (see 46 FR 8942; January 27, 1981).

Elsewhere in this issue of the **Federal Register,** FDA is staying until further notice, the effective date of the remaining provisions of the May 30, 1980 final rule.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 406, 409, 502, 503, 505, 507, 510, 513–516, 518–520, 701(a), 706, and 801, 52 Stat. 1049–1053 as amended, 1055, 1058 as amended, 59 Stat. 463 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–407 as amended, 76 Stat. 794–795 as amended, 90 Stat. 540–560, 562–574 (21 U.S.C. 346, 348, 352, 353,355, 357, 360,.360c–360f, 360h–360j, 371(a), 376, and 381)) and the Public Health Service Act (secs. 215, 351, 354–360F. 58 Stat. 690, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 262, 263b–263n)) and the Administrative Procedure Act (sec. 4. 60 Stat. 238 (5 U.S.C. 553)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) (formerly 5.1; see 46 FR 26052; May 11, 1981)), the effective date of §§ 50.1 and 50.3(b) published in the **Federal Register**

of May 30, 1980 (45 FR 36386) is changed to July 27, 1981.

Effective date. July 27, 1981.

Dated: June 29, 1981.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 81–19605 Filed 6–30–81; 11:56 am]

BILLING CODE 4110–03–M

---

21 CFR Part 50

[Docket No. 78N–0049]

Protection of Human Subjects; Prisoners Used as Subjects in Research; Stay of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; stay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is staying the effective date of its regulations establishing conditions under which biomedical research on prisoners will be accepted in satisfaction of FDA's regulatory requirements. All provisions of Subpart C of Part 50 of the final regulations are stayed pending reproposal of the subpart, including § 50.44 (21 CFR 50.44). The stay will remain in effect until final action taken on the reproposal is effective.

DATE: The stay will become effective on August 6, 1981.

FOR FURTHER INFORMATION CONTACT: Halyna P. Breslawec, Office of Health Affairs (HFY–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 30, 1980 (45 FR 36386), FDA adopted final regulations to provide protection for prisoners used as the subjects of biomedical research within the agency's jurisdiction. At that time, the agency announced that the regulations would become effective on June 1, 1981. On July 29, 1980, a lawsuit was filed in the United States District Court for the Eastern District of Michigan to have these regulations declared invalid. See *Fante and the Upjohn Co.* v. *Department of Health and Human Services, et al.,* Civil Action No. 80–72778. Because sponsors of research affected by the regulations might incur substantial compliance costs that would be wasted if the District Court declared the rule invalid, the agency published in the **Federal Register** of March 27, 1981 (46 FR 18951) a delay of the June 1, 1981 effective date and announced that the rule would become effective 5 months from the date of the District Court's final judgment on the merits of the lawsuit. The regulations are currently not enforceable and have no effect,

The agency has considered questions that have been raised concerning the need, utility, and costs of the current rule and has determined that it is appropriate to reconsider the regulations. FDA will in the near future repropose the regulations at which time it will provide for public comment on the reproposal. In the meantime, FDA is staying indefinitely the effective date of Subpart C of Part 50 to permit the agency to reach a final decision as to the content of the reproposed regulations. This action is taken under § 10.35(a) of FDA's administrative practices and procedures regulations (21 CFR 10.35(a)), which authorizes the agency to stay at any time the effective date of an action pending or following a decision on any matter.

The agency has determined that under the circumstances it would be impracticable, unnecessary, and contrary to the public interest to subject this action to public comment under the Administrative Procedure Act (5 U.S.C. 553(b)). The regulations affect the interests of a small number of persons because research on prisoners is now carried on at a very small number of prisons. Moreover, the stay itself will not prejudice the interests of any affected groups or individuals, because as a result of the March 27, 1981 notice, the regulations are not currently enforceable or in effect. The agency expects to publish a reproposal that will give the public an opportunity to comment before the earliest date on which the delayed rule could have become effective. Finally, if a stay pending reproposal is not imposed immediately, the government will be obliged to continue to defend the existing rule in the lawsuit that is now pending. In view of the decision to reconsider the regulations that are at issue in the lawsuit, continuing to defend the litigation would be a costly and needless use of public resources. Accordingly, the agency concludes that it has good cause to stay the effective date of Subpart C of 21 CFR Part 50 without providing for public comment.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 406, 409, 502, 503, 505, 507, 510, 513–516, 518–520, 701(a), 706, and 801, 52 Stat. 1049–1053 as amended, 1055, 1058 as amended, 59 Stat. 463 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–407 as amended, 76 Stat. 794–795 as amended, 90 Stat. 540–560, 562–574 (21 U.S.C. 346, 348, 352, 353, 355, 357, 360, 360c–360f, 360h–360j, 371(a), 376, and 381)) and the Public Health Service Act (secs. 215, 351, 354–360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 262, 263b–263n)) and the Administrative Procedure Act (sec. 4, 60 Stat. 238 (5 U.S.C. 553)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), the effective date of Subpart C of 21 CFR Part 50 published in the **Federal Register** of May 30, 1980 (45 FR 36386) is stayed until further notice. This notice supersedes the notice of March 27, 1981.

Effective date. The stay will become become effective August 6, 1981.

Dated: June 29, 1981.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 81–19606 Filed 6–30–81; 11:56 am]

BILLING CODE 4110–03–M

---

21 CFR Parts 74, 81, and 82

[Docket No. 76C–0044]

D&C Orange No. 10 and D&C Orange No. 11; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of April 28, 1981, of the regulations that permanently list D&C Orange No. 10 and D&C Orange No. 11 as color additives for use in externally applied drugs and cosmetics. (46 FR 18951, March 27, 1981)

DATE: Effective date confirmed: April 28, 1981.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: A final rule published in the **Federal Register** of March 27, 1981 (46 FR 18951) added D&C Orange No. 10 and D&C Orange No. 11 for use in externally applied drugs and cosmetics under §§ 74.1260 and 74.1261 (21 CFR 74.1260 and 74.1261) to Subpart B—Drugs and under §§ 74.2260 and 74.2261 (21 CFR 74.2260 and 74.2261) to Subpart C—Cosmetics of Part 74 (21 CFR Part 74). The final rule also amended Part 81 in § 81.1(b) (21 CFR 81.1(b)) by deleting D&C Orange No. 10 and D&C Orange No. 11 from the provisional lists of color additives; amended § 81.10(m) by terminating the provisional listing of D&C Orange No. 10 and D&C Orange No. 11 for use in ingested drugs and cosmetics; and amended § 81.30(n)(1) by cancelling the certificates for the color additives, their lakes and all mixtures containing these color additives as pertains to use of the additives in ingested drugs and