§ 204.2 Documents.

* * * * *

(g) * * *

(1) * * *

(i) * * *

(B) Evidence that the beneficiary was fathered by a United States citizen. The putative father must have been a United States citizen at the time of the beneficiary's birth or a United States citizen at the time of his death if he died prior to the beneficiary's birth. It is not required, however, that the name of the father be given. Submit as many documents as may be obtained, including, but not limited to:

(1) The beneficiary's birth and baptismal certificates or other religious documents;

(2) Local civil records;

(3) Affidavits from knowledgeable witnesses;

(4) Letters from, or evidence of financial support from the beneficiary's putative father;

(5) Photographs of the beneficiary's putative father, especially with the beneficiary; and

(6) Evidence of the putative father's United States citizenship.

* * * * *

(iii) * * *

(A) A favorable home study of the sponsor to be conducted by an agency legally authorized to conduct that study in the jurisdiction of placement or, if the sponsor is residing outside the United States, a home study conducted by any agency, and favorably recommended by an agency legally authorized to conduct home studies in the state of the sponsor's and beneficiary's intended residence in the United States.

* * * * *

(Sec. 201(b), 203(a)(1), 203(a)(4), and 204(g) of the Immigration and Nationality Act, as amended; 8 U.S.C. 1151(b), 1153(a)(1), 1153(a)(4), and 1154(g))

Dated: February 16, 1984.

Andrew J. Carmichael, Jr.,

Associate Commissioner, Examinations Immigration and Naturalization Service.

[FR Doc. 84-6074 Filed 3-6-84; 8:45 am]

BILLING CODE 4410-10-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

Environmental Qualification of Electric Equipment

AGENCY: Nuclear Regulatory Commission.

ACTION: Statement of Policy on Environmental Qualification.

SUMMARY: The United States Court of Appeals for the District of Columbia Circuit has vacated and remanded a Commission rule which removed from nuclear power plant operating licenses a June 30, 1982 deadline for the completion of the environmental qualification of certain safety-related electrical equipment.[1] *Union of Concerned Scientists* v. *Nuclear Regulatory Commission, et al.*, 711 F.2d 370 (D.C. Cir. 1983) (hereinafter "*UCS* v. *NRC*"). The Court remanded to the Commission with direction to obtain public comments on the current documentation justifying the continued operation of nuclear power plants pending the completion of the environmental qualification program. This Statement of Policy is intended to explain the Commission's response to the D.C. Circuit's remand and to describe other related actions the NRC will take until the conclusion of the rulemaking proceeding which the Commission intends to initiate by an accompanying Notice of Proposed Rulemaking.

SUPPLEMENTARY INFORMATION:

I. Background

To provide adequate protection of public health and safety, nuclear power reactors rely in part on engineered safety systems. The Commission has stated that "fundamental to NRC regulation of nuclear power reactors is the principle that safety systems must perform their intended function in spite of the environment which may result from postulated accidents. Confirmation that these systems will remain functional, under postulated accident conditions, constitutes environmental qualification." CLI-80-21, 11 NRC 707, 710 (1980). This principle is incorporated in the Commission's existing General Design Criteria One and Four. 10 CFR Part 50, Appendix A.

A June 30, 1982 deadline relating to environmental qualification of safety-related electrical equipment in operating nuclear power reactors, and the Commission's lifting of that deadline, came about as follows. In 1977 the Union of Concerned Scientists ("UCS") filed a petition with the Commission, asking among other things for a shutdown of those operating reactors containing electrical connectors that had been discovered by Sandia Laboratories not to be environmentally qualified. The Commission denied that shutdown request. However, a few plants were shut down for specific qualification deficiencies. Petition for Emergency and Remedial Action, CLI-78-6, 7 NRC 400, 410-415 (1978). In addition, the Commission directed the staff to review and evaluate the environmental qualification of all Class IE electrical equipment. CLI-78-6, 7 NRC 400 at 415 (1978). The NRC staff initiated that review by requesting licensees to determine the adequacy of existing documentation on equipment qualification. Circular 78-08. Many licensees failed to devote the level of attention the staff believed was necessary to this issue and requests for licensee action requiring written responses became necessary. IE Bulletins 79-01 and 79-01B were issued to request the necessary information.

Staff's reviews of licensees' submittals in response to 79-01 and 79-01B led to the discovery of more equipment for which qualification had not been established. Licensees either did not have the required documentation to demonstrate qualification or did not include the documentation requested in the bulletins. The documentation that was submitted by the licensees and reviewed by the staff consisted of summary data extracted from qualification test reports and analyses. These licensee submittals prompted UCS to petition the Commission to reconsider its previous denial of UCS's request for reactor shutdowns.

The Commission once again denied UCS's petition, finding that "current Commission requirements . . . and those actions we order today provide reasonable assurance that the public health and safety is being adequately protected during the time necessary for corrective action." *Petition for Emergency and Remedial Action*, CLI-80-21, 11 NRC 707, 709 (1980). Among the actions ordered by the Commission were: (1) The establishment of more specific environmental qualification criteria; and (2) the establishment of a June 30, 1982 deadline for completion by the licensees of the environmental qualification program. The deadline was incorporated into the individual licenses for operating plants by separate orders.

The experience outlined above had shown a generic deadline was necessary to assure a sustained licensee effort to complete the qualification program. The order establishing the deadline did not specify the enforcement action which would be taken in the event of non-compliance. 11 NRC at 712. In particular, the Commission made no finding that failure to meet the deadline would result in unsafe conditions requiring a plant shutdown.

Technical judgments regarding the sufficiency of licensee efforts and safety

[1] 47 FR 28363 (June 30, 1982). The deadline had originally been set by Commission Order, CLI-80-21, 11 NRC 707 (1980).

of continued operation were to be made by the staff on a case-by-case basis as the licensees provided further documentation on environmental qualification. Moreover, the public retained the opportunity pursuant to 10 CFR 2.206 to request NRC enforcement action at any particular plant. *Cf.* 11 NRC at 715. (If an interested person reviews the staff's written judgment on qualification and desires Commission review on that issue, that person may file a petition with the NRC staff pursuant to 10 CFR 2.202 and 10 CFR 2.206).

In response to Memorandum and Order CLI–80–21, and I&E Bulletin 79–01B, licensees continued to submit information on electrical equipment environmental qualification. In early 1981, the staff issued an Equipment Evaluation Report (EER) to each licensee of 71 operating nuclear power plants. The EER identified equipment for which the qualification information submitted in response to IE Bulletin 79–01B did not, in the staff's opinion, provide sufficient assurance of capability to perform required design functions in harsh environments. Under the provisions of 10 CFR 50.54(f), the staff requested each licensee to review the deficiencies enumerated and the ramifications thereof to determine whether safe operation of the plant would be affected. Each licensee responded that continued operation would not be unsafe.

In mid-1981, the staff sent a safety evaluation report (SER) to each licensee. The SER included the EER previously sent to the licensee, an evaluation of the environmental conditions specified by the licensee for environmental qualification purposes, an evaluation of the completeness of the list of safety-related equipment included in the qualification program, and the staff's conclusions with regard to compliance with Commission Memorandum and Order CLI–80–21. The SER also directed each licensee either to provide, within 90 days, documentation of the missing qualification information needed to demonstrate that the equipment with identified deficiencies was qualified or to commit to a corrective action such as requalification, replacement or relocation. If the latter option was chosen, the licensee was directed to provide a justification for continued operation (JCO) until such corrective action could be completed. All licensees provided responses to the mid-1981 SERs within the 90 days specified. These responses included additional technical information; justifications for continued operation or statements that such justifications were not required because in the licensee's opinion the equipment was qualified.

In late 1981, the NRC staff and Franklin Research Center (FRC) began in-depth reviews of all licensee responses to the issues raised in the SERs. This included looking at all of the background documentation provided by licensees in response to previous Commission Orders and SERs. This review was conducted in parallel with the staff's summary reviews for completeness of submittals and was not completed until the spring of 1983.

Evaluation of the information supporting licensee's JCOs was reviewed by the staff with the assistance of a consultant, FRC, in January 1982. The review was conducted over a very short period of time and consisted of checking the licensee's sumbittals to determine whether the justification for continued operation addressed all safety-related equipment which was listed in the plant SER as being of uncertain qualification. Where items of equipment were reported as qualified based on the licensee's reevaluation, no further justification was required at that time.

The FRC reviewed the JCOs using NRC-provided criteria.[2] The NRC project manager for each facility then reviewed the FRC's assessments of these JCOs. As a result of these reviews, FRC placed all responses in one of three categories. Category 1 plants (38) were those which at least asserted that either everything was qualified or provided justification for continued operation in light of the identified deficiencies. Category 2 plants (15) submitted responses which on their faces were not adequate for some reason. For example, they may not have addressed one or more pieces of equipment or deficiency identified in the SER. Category 3 plants (18) were those for which the submittal was completely inadequate. Staff required all Category 2 and 3 plants to submit further information to respond to the SERs and to provide justifications for continued operation. The level of detail contained in those JCO's ranged from summary assessments in some cases to extensive analyses in others. The staff reviewed these additional justifications and found them adequate. By the end of March 1982, then, all plants were in Category 1, pending an in-depth review of the supporting documentation. All licensees had aserted bases for qualification or justification for continued operation. The staff relied *primarily* on the licensees' assurances contained in these submittals in determining not to take immediate further action affecting the operation of the plant.

The volume of the submittals by the licensees showed that the extent of the effort necessary either to estabilsh the qualification of equipment or to replace unqualified equipment had been underestimated and that the June 30, 1982 deadline would not be met. Indeed, a group of NRC licensees petitioned the Commission to extend the June 30, 1982 deadline. The Commission proposed to extend the deadline in the NRC's proposed rule on environmenal qualification published for comment on January 20, 1982. In the rule the Commission proposed to codify the environmental qualification requirements set out in the existing order CLI–80–21. In addition, the proposed rule: (1) Requested licensees to submit analyses justifying continued operation pending completion of the environmental qualification program, and (2) established new compliance deadlines for completion of environmental qualification. 47 FR 2876, 2877–2878, January 20, 1982. The Commission expected the rulemaking, licensees' analyses, and staff's evaluations to be completed well in advance of the June 30, 1982 deadline which was then still in effect.

In late May of 1982 it became clear to the Commission that despite efforts by the staff, the final rule would not be promulgated before the June 30, 1982 deadline. Accordingly, on June 30, 1982, the Commission issued, without notice and opportunity for comment, an immediately effective rule suspending the June 30, 1982 compliance deadline incorporated in each operating license (OL) then in force. The Commission stated that licensees were expected to continue their efforts to meet the environmental qualification criteria standards established in CLI–80–21.

In making the rule immediately effective the Commission relied on the "good cause" exception to the rulemaking requirements of section 4 of the Administrative Procedure Act (APA). In the statement of consideration accompanying that rule, the Commission explained that "licensees should not be placed in jeopardy of enforcement action pending promulgation of a revised schedule for implementation of equipment qualification requirements."

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[2] The criteria are [either]:

1. Redundant equipment is available to substitute for the unqualified equipment; *or*

2. Another system is capable of providing the required function of the system with unqualified equipment; *or*

The unqualified equipment will have performed its safety function prior to failure; *and*

4. The plant can be safely shutdown in the absence of the unqualified equipment.

47 FR 28363 (June 30, 1982). The Commission also stated that the staff had received and evaluated each operating plant licensee's justification for continued operation. The statement of considerations added that, from these analyses,[3] the Commission had determined that continued operation of these plants pending completion of the equipment qualification program would not present undue risk to the public health and safety. *Id.*

Subsequently, the General Counsel interpreted this statement on safety of continued operation in a binding formal interpretation of the rule.[4] He found that the Commission's statement was an "explanation that before suspending the compliance deadline the Commission had reviewed the status of environmental qualification at each plant to determine that there were no widespread substantial qualification deficiencies which might indicate a need for industry-wide enforcement action." He noted that the rule did not preclude any interested person from filing a petition under 10 CFR 2.206 by citing specific qualification deficiencies as a basis for challenging the continued operation of a particular plant.

As a result of the Commission's lifting of the June 30, 1982 deadline, the staff conducted another brief review in late 1982, of the evaluations of the licensees' JCOs for the 33 plants for which additional information had previously been supplied to support the JCO review performed in early 1982. These reviews were performed to determine whether the JCOs remained adequate, given the anticipated adoption of the new deadline for qualifying electrical equipment. Staff reaffirmed that the JCOs remained adequate.

By April 1983, the staff and FRC completed their in-depth reviews begun in late 1981 on the licensees' responses to issues raised in the mid-1981 staff SERs for 71 operating reactors. These reviews consisted of an audit of equipment qualification data that the licensees had submitted throughout the course of these reviews. Based on NRC's analyses, the staff issued a second round of safety evaluation reports for each of the 71 operating plants. These SERs adopted the FRC's conclusions.

The SERs identified some deficiencies in licensees' submittals. As a result, staff issued transmittal and clarification letters which set forth deadlines for the licensees to provide the requested equipment environmental qualification information. For items found unqualified, the staff requested JCOs within 10 days of receipt of the SER. The additional information submitted by the affected licensees was reviewed by the staff and the issues resolved on the bases of the licensees': (1) Replacement of equipment, (2) provision of more information showing the equipment was qualified, or (3) provision of a JCO which satisfied the previously established criteria.

None of the items addressed in this round of review had been identified during the January 1982 assessment of the JCOs submitted by the licensees, because the initial reviews were based on summary data, extracted from test reports and analyses, submitted in response to IE Bulletin 79-01B, and on assertions made by the licensees that equipment was qualified. The major difference between the staff's previous findings and the current findings is that the technical bases for the staff's conclusions that certain qualification deficiencies exist have been specified in more detail as a result of FRC's completion of its review of the documentation submitted by licensees to support qualification of the equipment.

An initial examination of the licensees' responses to the second round staff SERs indicates that in a number of instances licensees maintain the position taken in response to the mid-1981 staff SER, *i.e.*, that much of the equipment challenged by the 1982-1983 second round SERs is in fact adequate to perform all required design functions and therefore justification for continued operation is not needed. In some instances there are new or additional test data, and some previously challenged equipment has been shown to be qualified. Finally, staff has found that some aspects of the licensees' responses raise technical issues requiring further analysis for their resolution, such a similarity, qualified life, and test sequences.

On January 6, 1983 the Commission promulgated a Final Rule on Environmental Qualification of Electrical Equipment Important to Safety, 10 CFR 50.49. That rule established general qualification criteria and new deadlines for compliance by 1985 for most plants.

II. The D.C. Circuit Decision

On June 30, 1983 the D.C. Circuit vacated the Commission's decision in promulgating the June 30, 1982 interim rule for failure to provide an opportunity to comment on "the sufficiency of current documentation purporting to justify continued operation pending completion of environmental qualification of safety-related eqipment."[5] The Court also stated that the final rule appears to be partially predicated on the Commission's conclusion that the safety of continued operation had been demonstrated by this documentation.[6] The Court did not criticize the substance of the Commission's determination, noting that "the NRC maintains constant vigilance over the safety of nuclear power plants and monitors compliance with safety requirements at each nuclear reactor on a day-to-day basis."[7]

III. The Current Situation

a. Staff Actions

The staff is currently implementing a program to complete the review of licensees' electrical equipment environmental qualification programs. This effort includes a one day meeting with each licensee of the 71 plants reviewed previously by the staff with the assistance of FRC. Discussion during each meeting includes the licensee's proposed/implemented method of resolution of the environmental qualification deficiencies identified in the 1982-1983 SER, compliance with the requirements set forth in 10 CFR 50.49 (EQ Rule), and justification for continued operation given those equipment items for which environmental qualification is not yet complete. Each licensee is required to document the results of the meeting in a subsequent submittal to the staff. Based on this submittal the staff will prepare and issue a final SER for each of the 71 plants that addresses the environmental qualification of electric equipment important to safety. This effort is scheduled to be completed during 1984.

b. Concerns Raised by Sandia National Laboratories

Sandia National Laboratories (Sandia), an NRC contractor, has recently expressed some concerns to the Commission regarding environmental qualification of electrical equipment. At a Commission meeting on January 6, 1984 Sandia representatives identified what they perceived as shortcomings in qualification methodologies and design bases (acceptance criteria), and the presence of inadequate equipment in plants. The staff prepared responses to the Sandia presentation and subsequently met with Sandia to assure

[3] The analyses accepted by the staff included licensee's assertions that the equipment was qualified, in their opinion. The review of the documental supporting these assertions was in the process of being reviewed by FRC at the time the interim rule was promulgated.

[4] 10 CFR 50.3.

[5] Slip op. at 27-28.

[6] *Id.* at 376.

[7] *Id.* at 383.

that the concerns had been interpreted and are being adequately addressed. Subsequent to this meeting, Sandia informed the staff that all concerns raised by Sandia regarding environmental qualification of electrical equipment, as defined by 10 CFR 50.49, "have been addressed" in the staff responses. Examples of staff's responses are discussed below.

Shortcomings in qualification methodologies are the subject of continuing research, and Sandia research tests have not demonstrated that nuclear plant safety equipment, properly qualified to existing qualification standards and NRC regulatory requirements, would not perform its safety functions. With regard to shortcomings in design bases (acceptance criteria), the staff is aware of the concerns expressed by Sandia and is addressing them in its reviews of licensee's equipment environmental qualifications programs. For example, Sandia believes that there may be shortcomings in the insulation resistance and leakage current values used as acceptance criteria for terminal blocks. Staff reviews these values when evaluating the environmental qualification of terminal blocks and requires that licensees either justify the values chosen for each particular use or provide justifications for continued operation with current values or change the values by using different terminal blocks.

The staff is also aware of Sandia's concern that some unqualified equipment remains in nuclear plants. These concerns are also being addressed by the staff in its review process, and are being resolved on a case-by-case basis. For example, Sandia reported that pressure switches failed when exposed to a high-pressure and steam-flash spray environment. Staff noted that no claims have been made that these switches are qualified for such an environment. These switches are not to be used in applications where they would experience such conditions. Staff takes into account such considerations when evaluating licensees' and applicants' qualification programs. In addition, an I&E information notice has been issued to licensees describing the results of the Sandia test of these switches, and stating the staff's position that such switches are not to be used where they would experience such environmental conditions.

A number of IE Information Notices have identified specific concerns with qualification of some components. All equipment which has not been shown to be qualified must either be demonstrated to be qualified, be replaced or relocated, or a justification for continued operation provided. Therefore, while Sandia identified potential generic issues with some equipment components, the staff has concluded that none of the issues identified would warrant generic safety-related enforcement action at this time.

c. Sandia Annual Report

Sandia recently issued its Fiscal Year 1983 annual report on the Environmental Qualification Inspection Program of organizations involved in equipment qualification efforts. The report provides examples of qualification problems to highlight issues raised during those inspections for which Sandia provided technical consultant support to the staff. The Sandia concerns discussed during the Commission Meeting of January 6, 1984 were derived in part from the inspection results described in this annual report. The report illustrates some industry practices that could be improved and identifies areas where additional NRC guidance may be useful. The staff discussed the contents of this report with Sandia, and has concluded, that the report does not suggest that generic safety related enforcement action is necessary as a result of Sandia's concerns. Where inspections or reports received by the staff have indicated reasons to question qualification of equipment, the staff has required licensees to take actions including the replacement of equipment or provision of justifications for continued operation.

d. UCS Petition

On February 7, 1984, the Union of Concerned Scientists (UCS) petitioned the Commission to take certain actions regarding some recent developments in the environmental qualification of electrical equipment. These developments were: (1) Recent notices from the Commission's Office of Inspection and Enforcement to utility licensees and Atomic Safety and Licensing Boards reporting deficiencies in the environmental qualification of a few components commonly used in licensed facilities; (2) a report by the Sandia National Laboratory (Sandia) questioning the validity of certain environmental qualification tests; and (3) recent comments by Sandia to the Commission regarding Sandia's coordination with the NRC staff on research on environmental qualification. In UCS's view, these developments indicate that the NRC staff has failed to handle properly the Commission's environmental qualification program.

Accordingly, UCS has requested the Commission to review the staff's conduct of the environmental qualification program and to direct the staff to address the matters identified by the UCS. Specifically, UCS has requested that the Commission, among other things, direct staff to: (1) Obtain and evaluate justifications for continued operation for plants using the deficient components reported by the Office of Inspection and Enforcement; (2) review the generic implications of Sandia's concerns about tests of environmental qualification; and (3) direct the staff to require utilities to justify continued operation promptly after receiving notices of environmental deficiencies. UCS has also requested Commission to direct holders of construction permits to cease construction involving deficient components until these components are qualified and to direct Atomic Safety and Licensing Boards not to authorize issuance of operating licenses until deficient components have been qualified or replaced.

"The Commission is currently considering UCS's Petition in light of this Policy Statement and accompanying Notice of Proposed Rulemaking."

IV. Current Commission Policy

As indicated above, over the past several years power reactor licensees have devoted extensive efforts to comply with the Commission's environmental qualification requirements. Progress on licensee compliance has been monitored by the NRC, and NRC's own review efforts have been extensive. There have been two rounds of progressively more detailed safety evaluations for all operating reactors and additional reviews of the various rounds of JCOs.

The environmental qualification of electrical equipment throughout a nuclear power plant to standards higher than those existing at the time the plant was licensed has proved to be a complex and difficult task. Thousands of individual pieces of equipment must be identified; qualification data for this equipment must be examined and compared to applicable standards; test programs must be carried out where data is lacking; and equipment must be replaced if necessary. In many cases equipment can be replaced only when the plant is shut down. During such downtime licensees have many tasks to accomplish in addition to equipment qualification efforts. Delays may also result from the unavailability of qualified equipment and difficulties in testing existing equipment. The performance of industry in the area of

environmental qualification has improved with time.

The environmental qualification problem at individual plants is too varied to warrant generic safety-related enforcement action. Instead it has been and continues to be the Commission's policy to monitor closely each licensee's progress on environmental qualification and to take enforcement action for safety reasons on a case-by-case basis. To this end, the staff intends to follow the guidelines described below in conducting its individual reviews.

(1) Evidence of environmental qualification deficiencies which would prevent a plant from going to and maintaining a safe shut down condition in the event of a design basis accident will be the basis for enforcement action. Enforcement action will generally not be taken where a licensee has asserted that operation will not involve undue risk, unless the staff has determined that continued operation cannot be justified. The Commission recognizes that this policy will permit power plants to continue to operate where licensees' assertions of qualification are still undergoing staff review. The Commission believes that this course of action is required unless the staff concludes that the justification for continued operation (JCO) reveals a deficiency requiring shutdown.

There are persuasive technical and policy reasons why licensees' assertions and analyses may be relied on pending independent NRC staff review. The Commission notes that licensees received their operating licenses after extensive staff reviews including, in many cases, adjudicatory hearings. These proceedings include a determination that the licensee is technically capable of operating the plant safely. The mere existence of a safety uncertainty that needs to be evaluated does not, in the Commission's view, provide a basis for shutdown or similar enforcement action. It is the purpose of the case specific NRC staff reviews to determine whether, in any given case, sufficient evidence exists that would support enforcement action. In addition to confirmation of significant safety deficiencies, a persistent refusal by a licensee to cooperate adequately with the Commission's environmental qualification program would be a basis for enforcement action. But the Commission's experience with the ongoing review of licensee progress on environmental qualification, as described above, has not suggested any general refusal on the part of licensees to make reasonable efforts. Thus the June 30, 1982 deadline has served its intended purpose to assure reasonable licensee efforts and therefore need not be enforced. The June 30, 1982 deadline was not a generic cut-off date for operation. Rather, the June 30, 1982 deadline was established to force licensee completion of the environmental qualification program in a reasonable time. Since the deadline itself has proved unrealistic, and since licensees are making reasonable efforts to achieve environmental qualification, the Commission has concluded that retention of the June 30, 1982 deadline is neither necessary nor desirable as a general matter. The safety of operation of plants continues to be reviewed on an individual basis. The Commission's authority to take individual enforcement action for safety reasons, including shutdowns, is not dependent on the presence in individual licenses of a requirement for environmental qualification by a certain date.

(2) In the interim, if any person believes that there is information indicating that specific qualification deficiencies or other reasons related to environmental qualification require enforcement action at a particular plant, such information should be presented to the Director, NRR pursuant to 10 CFR 2.206. Within 45 days of the close of the comment period in the rulemaking initiated today by companion notice, the Director, NRR will report to the Commission on any generic issues raised by any comments on plant specific qualification issues.

The Commission's final rule is still in effect. That rule established new compliance deadlines which have not yet passed. It was the Commission's intention that the compliance schedule in the final rule should supersede previous deadlines. Because the Court's decision in *UCS* v. *NRC* may have created uncertainty regarding the current status of the June 30, 1982 compliance deadline in each facility operating license, the Commission will conduct a notice and comment rulemaking proceeding to delete formally that deadline from all licenses.

Dated at Washington, DC, this 1st day of March, 1984.

Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 84-6075 Filed 3-6-84; 8:45 am]

BILLING CODE 7590-01-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1214

Space Transportation System; Duty-Free Entry of Space Articles

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: This regulation prescribes NASA's policy and procedures with respect to the duty-free entry of articles imported to be launched into space by NASA, including spare parts or necessary and uniquely associated support equipment in connection with a launch into space. The intent of this regulation is to provide guidance on the use of the Administration's authority to certify that space articles may be imported duty-free.

EFFECTIVE DATE: March 7, 1984.

FOR FURTHER INFORMATION CONTACT: Robert J. Wojtal, Office of General Counsel, Code GK, NASA Headquarters, Washington, DC 20546. Telephone 453-2446.

SUPPLEMENTARY INFORMATION: On November 18, 1983, NASA issued for public comment a proposed rule to prescribe NASA's policy and procedures with respect to the duty-free entry of articles imported to be launched into space by NASA, including spare parts of necessary and uniquely associated support equipment in connection with a launch into space (48 FR 52480). No comments were received by NASA. Accordingly, NASA is adopting the proposed rule without change.

The National Aeronautics and Space Administration has determined that:

1. The rule is not subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601-612, since it will not exert a significant economic impact on a substantial number of small entities. It is applicable only to those persons or entities who import into the United States materials to be launched in space by NASA, including spare parts or necessary and uniquely associated support equipment in connection with a launch into space.

2. The rule is not a major rule as defined in Executive Order 12291 (46 FR 13193, February 19, 1981).

List of Subjects in 14 CFR Part 1214

Payload specialist, Mission, Mission manager, NASA-related payload, Mission specialist, Investigator working group, Government employees, Government procurement, Security

measures, Space transportation and exploration, Space Shuttle.

PART 1214—SPACE TRANSPORTATION SYSTEM

14 CFR Part 1214 is amended by adding a new Subpart 1214.15 to read as follows:

Subpart 1214.15—Duty-Free Entry of Space Articles

Sec.

Authority: Section 116 and 156 of Pub. L. 97–446, 96 Stat. 2335–2336 and 2345–2346 (19 U.S.C. 1202 note).

Subpart 1214.15—Duty-Free Entry of Space Articles

§ 1214.1500 Scope.

This subpart sets forth NASA's policy and procedures with respect to authorizing the duty-free entry of articles imported into the United States by any person or entity which are to be launched into space by NASA, including spare parts or necessary and uniquely associated support equipment in connection with a launch into space. It also deals with the duty-free entry of articles returned from space by NASA.

§ 1214.1501 Applicability.

This subpart applies to qualifying articles entered or withdrawn from warehouse for consumption in the customs territory of the United States between January 27, 1983, and December 31, 1994, and to articles returned from space by NASA.

§ 1214.1502 Background.

In order to encourage and facilitate the use of NASA's launch services for the exploration and use of space, section 116 of Pub. L. 97–446 provides for the duty-free entry into the United States of certain articles that meet the following two conditions: First, the articles must be imported for NASA for its space related activities or the articles must be imported by another person or entity for the purpose of meeting its obligations under a launch services agreement with NASA. Second, NASA must certify to the Commissioner of Customs that the articles to be entered duty-free are to be imported to be launched into space or are spare parts or necessary and uniquely associated support equipment for use in connection with a launch into space. This exemption from duty is provided for in item 837.00, Tariff Schedules of the United States (19 U.S.C. 1202 note). Section 116 of Pub. L. 97–446 also provides for the duty-free entry into the United States of articles returned from space by NASA.

§ 1214.1503 Authority to certify.

(a) The following NASA officials and their deputies are authorized, under the conditions described herein, to make the certification to the Commissioner of Customs required for the duty-free entry of space articles pursuant to item 837.00, Tariff Schedules of the United States (19 U.S.C. 1202, note). No further redelegation is authorized.

(1) The NASA Assistant Administrator for Procurement is authorized to issue the certification for articles imported into the United States which are procured by NASA or by other U.S. Government agencies, or by U.S. Government contractors or subcontractors when title to the articles is or will be vested in the U.S. Government pursuant to the terms of the contract or subcontract. Requests for certification should be sent to: H/Assistant Administrator for Procurement, Attn: HP/Director, Procurement Policy Division, National Aeronautics and Space Administration, Washington, DC 20546.

(2) The NASA Associate Administrator for External Relations is authorized to issue the certification for articles imported into the United States pursuant to international cooperative agreements. Requests for certification should be sent to: L/Associate Administrator for External Relations, Attn: LI/Director, International Affairs Division, National Aeronautics and Space Administration, Washington, DC 20546.

(3) The NASA Associate Administrator for Space Flight is authorized to issue the certification for articles imported into the United States by persons or entities or under agreements other than those identified in paragraphs (1) and (2) of this section. Requests for certification should be sent to: M/Associate Administrator for Space Flight, Attn: MC/Director, Customer Services Division, National Aeronautics and Space Administration, Washington, DC 20546.

(b) Each request for certification shall be reviewed by the Office of the NASA Comptroller and the Office of General Counsel and their concurrence obtained by the certifying official.

(c) To the extent an authorized NASA official approves a request for certification, that official shall sign a certificate in the following form:

Articles for the National Aeronautics and Space Administration, Item 837.00, TSUS

I certify that the articles identified in ——— attached, are articles to be imported to be launched into space, spare parts, or necessary and uniquely associated support equipment for use in connection with a launch into space in accordance with item 837.00, Tariff Schedules of the United States.

Name ———

Date ———

(d) A blanket certificate for one or more launches for a launch customer is authorized but shall require written verification by a NASA official designated by a Director of a receiving NASA Installation that the articles imported meet the conditions of the certificate. The blanket certificate shall be in the following form but may be reasonably revised to accord with the circumstances.

Articles for the National Aeronautics and Space Administration, Item 837.00, TSUS

I certify that the articles for the launch of ——— payload(s) pursuant to the NASA Launch and Associated Services Agreement No. ———, dated ——— with ——— are articles to be launched into space, spare parts, or necessary and uniquely associated support equipment for use in connection with a launch into space, in accordance with item 837.00, Tariff Schedules of the United States. The necessary and uniquely associated support equipment is identified in ——— attached.

Before this certificate is used to obtain the duty-free entry of these articles, a cognizant NASA official at the receiving NASA Installation who is designated by the Installation Director shall verify in writing that specifically identified articles to be entered on a particular date are the articles described in this certificate. This verification and this certificate shall be presented to the U.S. Customs Service at the time entry for the particular articles is sought.

Name ———

Date ———

With respect to articles represented to be necessary and uniquely associated support equipment, the NASA official issuing the blanket certificate shall review these articles and approve their eligibility for duty-free entry. A description of these articles should be referred to in the blanket certificate and should be attached to it.

§ 1214.1504 Procedures.

(a) Request for certification shall be forwarded to the appropriate NASA official who has authority to certify as provided for in § 1214.1503.

(b) Each request for certification shall be accompanied by:

(1) A proposed certificate as provided for in § 1214.1503;

(2) The information and documentation required by 19 CFR 10.102(a);

(3) A statement with respect to each article, or each class of articles if all items in the class are substantially identical whether (i) the article is to be launched into space by NASA (identify the launch agreement, launch vehicle and launch date(s)); or (ii) it is a spare part to an article to be launched into space; or (iii) it is necessary or uniquely associated support equipment for use in connection with a launch into space.

(4) If the article is represented to be necessary and uniquely associated support equipment for use in connection with a launch into space, with respect to each such article or each such class of articles to be imported, explain why it is necessary and unique; and if the article may be used in connection with an activity other than a launch into space, whether or not it is intended to be so used. If it may be used in such other activity, NASA shall require, of non-U.S. Government agencies, as a condition to obtaining duty-free entry under this subpart, the customer to agree in the relevant NASA launch agreement not to use or in any manner dispose of those articles in the United States other than in connection with a launch into space; and

(5) The anticipated date of entry and port of entry for each article. If the article is to be transported in bond from the port of arrival to another port of entry in the United States, identify both ports.

(c) The signed certificate and its attachment will be forwarded to the NASA installation responsible for the duty-free entry of the materials. The procedures specified in 19 CFR 10.102 will be followed by the NASA installation in obtaining duty-free entry at the Customs port of entry. The NASA installation should ensure that, at the time the articles are to be released after Customs entry, the custody of the imported articles is transferred directly from the carrier or from the U.S. Customs Service to the NASA launch service customer or its agent.

(d) If articles procured under contract by NASA are imported prior to compliance with these procedures and it is essential that the articles be released from Customs custody prior to such compliance, the procedures outlined in 19 CFR 10.101 may be followed by cognizant NASA officials to secure the release of the articles from Customs custody. To the extent applicable, the procedures in § 1214.1504 shall be followed when time permits to obtain duty-free entry for the articles released from Customs custody.

§ 1214.1505 Necessary and uniquely associated support equipment.

The NASA certifying officer should take into account the following criteria in determining whether an article is necessary and uniquely associated support equipment in connection with a launch into space. Applicability of one or more of the following non-exclusive criteria lends support to the conclusion that the article is necessary and uniquely associated support equipment.

(a) The article has been designed and manufactured solely to support the launch of a payload or launch vehicle.

(b) A standard article has been modified in a substantial and extraordinary way considering its physical or functional characteristics solely to support launch of a payload or launch vehicle.

(c) The article's potential use is limited to support the launch of a payload or launch vehicle.

(d) The article is available only from a source outside of the Unites States.

(e) The article is a component of a system purchased outside of the United States.

(f) The article is to be exported from the United States upon completion of its use as support equipment.

§ 1214.1506 Articles returned from space.

Pursuant to section 116 of Pub. L. 97-446, the return of articles from space by NASA shall not be considered an importation, and an entry of such materials through the U.S. Customs Service shall not be required. This provision is applicable to articles returned by NASA from space whether or not the articles were launched into space onboard a NASA launch vehicle.

James M. Beggs,

Administrator.

[FR Doc. 84-5928 Filed 3-6-84; 8:45 am]

BILLING CODE 7510-01-M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1101

Information Disclosure Under Section 6(b) of the Consumer Product Safety Act; Correction

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule: Correction.

SUMMARY: This document corrects a final interpretive rule containing the Consumer Product Safety Commission's policy and procedure for disclosing to the public information from which the public can readily ascertain the identity of the manufacturer or private labeler of a consumer product. The rule interprets section 6(b) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2055(b). The rule appeared at pages 57406-57437 in the **Federal Register** of Thursday, December 29, 1983 (48 FR 57406-57437). The action is necessary to correct typographical errors.

FOR FURTHER INFORMATION CONTACT: Michael J. Gidding, Attorney, Office of the General Counsel, (301) 492-6980.

The following corrections are made in the **Federal Register** issue of December 29, 1983:

1. On pages 57407 the 18th line of the first full paragraph in column one under § 1101.11(a), "aristing" is corrected to read "arising."

2. On pages 57426 in the first column at the bottom under § 1101.45, the last four lines reading "docket maintained in 6 (b)(1) through (b)(3). The Commission declines therefore to adopt the commenter's recommendation" should be corrected to read "docket maintained in" and the balance of the lines should be eliminated.

On page 57426 in the second column "Section 1101.45 Adjudicatory Proceeding Exception" and the two paragraphs under it should be eliminated.

On page 57426 in the middle of the second column, the heading "Section 1101.46 Other Administrative or Judicial Exception," the first 12 lines of the first paragraph under that heading and the word "grant" in the beginning of the 13th line, should be eliminated.

On page 57433 near the top of the second column "§ 1101.3 General requirements." Should be corrected to read "§ 1101.31 General requirements."

On page 57435, third column, § 1101.45, the third line of paragraph (c) reading "the adjudication, whether in documents" should be corrected to read "the adjudication, whether in documents filed or".

On page 57435 third column, § 1101.45, the fourth line in paragraph (c) reading "exchanged during discovery filed or in" should be corrected to read "exchanged during discovery, or in".

* * * * *

Dated: March 1, 1984.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 84-6077 Filed 3-6-84; 8:45 am]

BILLING CODE 6355-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 74, 81, and 82

[Docket Nos. 76N-0366 and 83C-0128]

D&C Yellow No. 10; Listing as a Color Additive in Drugs and Cosmetics; Termination of Stay, Confirmation of Effective Date, and Further Amendment

AGENCY: Food and Drug Administration.

ACTION: Final rule; termination of stay, confirmation of effective date, and further amendment.

SUMMARY: The Food and Drug Administration (FDA) is terminating the stay of the regulations for the "permanent" listing of D&C Yellow No. 10 for use in drugs and cosmetics, excluding use in the area of the eye. The regulations were stayed by the filing of three objections under the formal rulemaking provisions of the Federal Food, Drug, and Cosmetic Act (the act) while FDA evaluated and acted on the objections. In response to two of the objections, FDA is amending the final rule to remove restrictions on use of D&C Yellow No. 10 in drugs and cosmetics and to provide for use of this color additive in drugs and cosmetics generally, excluding use in the area of the eye, in amounts consistent with current good manufacturing practice (CGMP). However, FDA is rejecting the third objection, which questions the specifications that the agency has established, because it is without merit. This document, therefore, terminates the stay of the final rule that permanently lists D&C Yellow No. 10; confirms the September 30, 1983 effective date for the final rule; removes D&C Yellow No. 10 from provisional listing for use in drugs and cosmetics; and amends §§ 74.1710(c) and 74.2710(b) (21 CFR 74.1710(c) and 74.2710(b)) (uses and restrictions).

DATES: Effective date confirmed for August 30, 1983 document (48 FR 39217): September 30, 1983; effective date of this document's April 9 1984; objections to the amendments by April 6, 1984.

ADDRESS: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James H. Maryanski, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. 202-472-5740.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published a final rule on August 30, 1983 (48 FR 39217), that amended the color additive regulations by permanently listing D&C Yellow No. 10. The final rule added § 74.1710, which lists D&C Yellow No. 10 for use in coloring drugs, and § 74.2710, which lists D&C Yellow No. 10 for use in coloring cosmetics, excluding use in the area of the eye. The final rule also amended § 81.1(b) (21 CFR 81.1(b)); § 81.25 (a)(1), (b)(1)(i), and (c)(1) (21 CFR 81.25 (a)(1), (b)(1)(i), and (c)(1)); and § 81.27(d) (21 CFR 81.27(d)) by removing the entries for D&C Yellow No. 10 from these regulations. Finally, the final rule revised § 82.1710 (21 CFR 82.1710) to state that D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710 (a)(1) and (b).

In the final rule, FDA gave interested persons until September 29, 1983, to file objections. Concurrently with publication of the final rule on August 30, FDA extended the closing date for the provisional listing of D&C Yellow No. 10 until November 1, 1983 (48 FR 39220), to provide time for the receipt and evaluation of objections. The agency received objections to the permanent listing regulations from two of the petitioners, the Certified Color Manufacturers' Association (CCMA) and the Pharmaceutical Manufacturers Association (PMA), and from a manufacturer of the color additive, H. Kohnstamm & Co., Inc. The objections are on file in the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this document. No requests for a hearing were received in response to the listing regulation.

To provide FDA time to evaluate and to act on these objections, the agency extended the provisional listing of D&C Yellow No. 10 to January 3, 1984, by a final rule published in the **Federal Register** of November 1, 1983 (48 FR 50311). FDA announced in that final rule that the regulations that permanently listed D&C Yellow No. 10 for use in drugs and cosmetics were stayed pending final agency action on the objections. Because FDA's review and evaluation of the objections required more time than the agency anticipated, FDA extended the closing date for the provisional listing of D&C Yellow No. 10 until March 5, 1984, in a final rule published in the **Federal Register** of January 3, 1984 (49 FR 61).

After evaluating the three objections, the agency finds that none presents issues of fact that warrant a hearing (21 CFR 12.24(b)). The objections and the agency's responses to them are summarized below.

II. Objections and Agency Responses

1. CCMA objected to the specifications that FDA established for 2-2(-quinolinyl)-1*H*-indene-1,3(2H)-dione (D&C Yellow No. 11) and for other diethyl ether soluble matter (principally chlorinated D&C Yellow (No. 11) in D&C Yellow No. 10. CCMA objected that the agency had not provided adequate notice of its intent to establish new specifications for the color additive. CCMA also objected that FDA had not provided manufacturers with an ample opportunity to test the reliability of the analytical method that the agency used to establish the specifications for the D&C Yellow No. 11 and chlorinated D&C Yellow No. 11 impurities in D&C Yellow No. 10. CCMA questioned the validity of this analytical method because the levels of these impurities in the toxicological samples used to establish the specifications were significantly lower than the levels of those impurities detected in 25 batches of D&C Yellow No. 10 certified over the past 3 years. CCMA claimed that the toxicological samples of D&C Yellow No. 10 used in the chronic feeding studies were routine batches of the color additive. CCMA asserted that the specifications might preclude the manufacture of D&C Yellow No. 10 for the foreseeable future. The objection requested a 180-day stay of § 74.1710(b) to allow manufacturers an opportunity to become familiar with the analytical method FDA used, to modify manufacturing processes, and to produce and to certify new batches of the color additive in accordance with the listing regulations.

FDA finds that this objection is without merit. The agency has followed the appropriate procedures in adopting the specifications in §74.1710(b) for D&C Yellow No 10, including adequate opportunities for CCMA to participate in the rulemaking pursuant to sections 701(e) and 706(d) of the act (21 U.S.C. 371(e) and 376(d)). Furthermore, the specifications that the agency has established also are appropriate.

Section 706(b)(3) of the act (21 U.S.C. 376(b)(3)) states that the regulations permanently listing a color additive shall, to the extent necessary to assure the safety of the use or uses for which the additive is being listed, prescribe the conditions under which such additive may be safely employed for such use or uses. Section 706(c) of the act (21 U.S.C. 376(c)) makes clear that among the conditions that the agency can establish under section 706(b)(3) are

specifications on the purity of the color additive.

The proceeding to list D&C Yellow No. 10 was begun by the filing of a petition by CCMA, PMA, and a third organization. In accordance with section 701(e)(1) of the act, FDA published a notice of the filing of that petition in the **Federal Register** of November 20 1968 (33 FR 17205). The agency acted on that petition in the final rule of August 30, 1983. Under section 701(e)(2) of the act, any person who was adversely affected by that final rule was able to file an objection with FDA. The agency announced this opportunity to file an objection in the final rule (48 FR 39220), and CCMA responded by filing an objection. CCMA was thus given its full procedural rights under the applicable provisions of the act. Its claim to the contrary is without legal support.

Because of the toxicological concerns it expressed in the final rule for the presence of D&C Yellow No. 11 in D&C Yellow No. 10 (48 FR 39218), FDA recognized that it needed to establish a specification for this impurity to assure the safety of the color additive. To meet this need, FDA developed a new, sensitive high pressure liquid chromatography (HPLC) method to analyze for D&C Yellow No. 11 in D&C Yellow No. 10. Using this method, FDA detected a chlorinated form of D&C Yellow No. 11 as well as D&C Yellow No. 11 in samples of D&C Yellow No. 10. Because data to establish the safety of the chlorinated D&C Yellow No. 11 impurity were not available, FDA concluded that a specification based on the levels of this impurity in the toxicological samples should also be established. Analyses by the new method showed that the toxicological samples contained significantly lower levels of D&C Yellow No. 11 and chlorinated D&C Yellow No. 11 than the most recently certified commercial batches of the color additive. FDA conducted studies that validated the HPLC method for detection of D&C Yellow No. 11 at the levels found in the toxicological samples. Similar studies were not performed for chlorinated D&C Yellow No. 11 because samples of this impurity were not available for use in such studies. FDA performed duplicate analyses of the toxicological samples to establish that the method was reliable. Data on the HPLC method, including the results of the FDA's analysis of batches of D&C Yellow No. 10, are on file at the Dockets Management Branch under the docket number listed in the heading of this document.

Limited additional data on the agency's analytical method were provided by a collaborative study performed by several independent laboratories at the request of CCMA. In this study, a composite sample of D&C Yellow No. 10 claimed to be typical of the material in commerce was analyzed in accordance with FDA's HPLC analytical method for D&C Yellow No. 11 and chlorinated D&C Yellow No. 11. Data from this study show that four of the five participating laboratories found similar levels of D&C Yellow No. 11 and chlorinated D&C Yellow No. 11 in the composite commercial sample. The levels of D&C Yellow No. 11 and chlorinated D&C Yellow No. 11 found in the composite sample were consistent with the levels FDA had previously found in recent commercial batches of D&C Yellow No. 10. Furthermore, although the collaborative study was not designed to test the reliability of the analytical method at the levels prescribed by the listing regulation, three participating laboratories, including FDA, did submit data for comparative purposes on their analyses of the toxicological sample of D&C Yellow No. 10. Although the summary of the collaborative study states that it was not clear that all three laboratories analyzed the same toxicological sample, the laboratories all reported levels of D&C Yellow No. 11 and chlorinated D&C Yellow No. 11 that were consistent with the levels that the agency had found in the toxicological sample and used as the basis for the specifications for these impurities in the listing regulation.

Thus, based on the available evidence, FDA concludes that the method it used to establish the specifications for D&C Yellow No. 11 and chlorinated D&C Yellow No. 11 was adequate and appropriate. The objection did not present any evidence to the contrary.

FDA has no information concerning the manufacture of D&C Yellow No. 10 that would account for the disparity it found in the levels of these impurities in the toxicological samples and in the commercial batches. Whatever the reason for the disparity, FDA finds that to assure the safety of the use of D&C Yellow No. 10, the specifications for this color additive must be based on the toxicological samples.

The results of the chronic feeding studies establish to a reasonable certainty that batches of the color additive that conform to the toxicological samples will not cause harm. The agency has no such assurance about batches of the color additive that contain higher levels of D&C Yellow No. 11 and chlorinated D&C Yellow No. 11. Because of the toxicological concerns about these impurities that the agency discussed in the preamble to the August 30, 1983 final rule, the agency cannot find that use of a batch of D&C Yellow No. 10 that contains greater amounts of these impurities than were in the toxicological samples is safe. (FDA has requested that D&C Yellow No. 11 be included in the bioassay program of the National Toxicology Program (NTP). On January 9, 1984 (49 FR 1139), NTP published a notice in the **Federal Register** nominating D&C Yellow No. 11 for toxicological testing.)

As for CCMA's request for a 180-day stay, FDA notes that it has taken the agency approximately that length of time to prepare this document. During that time, aside from requesting that the collaborative study discussed above be performed, CCMA has not reported to the agency on its efforts, if any, to modify the manufacturing process for D&C Yellow No. 10 or to produce the color additive in accordance with the specifications set forth in § 74.1710(b). Therefore, the agency concludes that a further stay of the listing regulation is not warranted.

2. PMA and H. Kohnstamm & Co., Inc., both objected to § 74.1710(c), which states that D&C Yellow No. 10 may be safely used for coloring drugs generally in amounts not to exceed 10 milligrams (mg) per daily dose of the drug. They pointed out that this 10 mg dose limitation is the same as the temporary tolerance that FDA established on the use of this color additive on August 21, 1979 (44 FR 48964). The objections reminded FDA that when the agency established that temporary tolerance, it promised that when the testing of D&C Yellow No. 10 was complete, as part of its decision on whether to list permanently the use of this color additive, it would reevaluate the need for the limitations on the additive's use. The objections stated that FDA had established the 10 mg per daily dose temporary tolerance on the basis of an acceptable daily intake of 30 mg per day, which was based on a safe dose of 0.1 percent (the highest dose that had been tested at the time the temporary tolerance was established) in animal feeding studies. The objections argued that a limitation on the use of this color additive in drugs has been shown not to be necessary by the recent chronic studies, which demonstrated a no-effect level of two percent in the rat. That no-effect level corresponds to an acceptable daily intake of 600 mg per day for a 60-kilogram person (48 FR 39218). The objections asked that § 74.1710(c) therefore be revised to

provide for the use of D&C Yellow No. 10 in drugs in amounts consistent with CGMP.

When the agency decided to grant the petition on D&C Yellow No. 10, it did not consider an increase in the level of the color additive permitted for use in drugs to be necessary. The agency was aware of a 1976 survey conducted by PMA on the use of color additives in drugs which showed that 70 percent of the drugs in which D&C Yellow No. 10 was used contained the color additive at levels of less than 2 mg per daily dose.

However, in response to the objections, FDA has carefully considered whether the limitations on the use of D&C Yellow No. 10 in drugs are necessary. Based on all of the information available to the agency, including data from the recent chronic feeding studies, the agency agrees that the tolerance of 10 mg per daily dose of the drug is not necessary to protect the public health.

FDA considered several factors in reaching this conclusion:

First, the agency considered whether the additional exposure to the color additive that would result from its use under conditions of CGMP would be safe. FDA estimates that under these conditions of use, the lifetime averaged exposure from D&C Yellow No. 10 in drugs is not likely to exceed 13 mg per day. (See Memorandum to File from T. Troxell, December 5, 1983; Entry No. 201 in documents on file with the Dockets Management Branch under Docket No. 83C–0128.) As stated in the objections, the acceptable daily intake for humans estimated from the recent chronic toxicity studies is 600 mg per day.

Second, the agency considered the potential exposure to D&C Yellow No. 11 that may result from an increase in the use of D&C Yellow No. 10 if its conditions of use are limited only by CGMP. The agency is confident, based on the results of the chronic feeding studies, that the specifications that it has established in § 74.1710(b) for D&C Yellow No. 11 and chlorinated D&C Yellow No. 11 are adequate to assure that even without the 10 mg per daily dose of drug limitation, exposure to these impurities will not pose a public health hazard.

Therefore, under 21 CFR 12.26, FDA is modifying § 74.1710(c) to provide for the use of D&C Yellow No. 10 in drugs generally in amounts consistent with CGMP.

3. H. Kohnstamm & Co., Inc., additionally requested that § 74.2710(b) be amended to delete the limitation on the use of D&C Yellow No. 10 in lipsticks and to provide for the use of the color additive for coloring cosmetics generally, except for use in the area of the eye, in amounts consistent with CGMP.

FDA agrees that the limitation on the use of D&C Yellow No. 10 for coloring lipsticks and other cosmetics intended to be applied to the lips is no longer necessary. The exposure to the color additive from these uses is low compared with the exposure from drugs. FDA, therefore, is amending § 74.2710(b) to provide for the use of D&C Yellow No. 10 in cosmetics generally (including lipsticks and other cosmetics intended to be applied to the lips) in amounts consistent with CGMP.

4. H. Kohnstamm & Co., Inc., also stated that the listing regulation did not specify the level of the color additive permitted for use in mouthwashes and dentifrices. The firm asserted that the permitted level of use of the color additive in these products is, therefore, unclear.

In the August 30, 1983 final rule, FDA intended § 74.2710 to include the use of D&C Yellow No. 10 in cosmetics generally, including mouthwashes. Similarly, it intended § 74.2710 to include the use of this color additive in dentifrices. The agency does not believe that a separate listing for mouthwashes and dentifrices in the final rule is necessary. The permanent listing, as amended below, should eliminate any confusion in this regard. It provides for the use of D&C Yellow No. 10 in both drugs and cosmetics generally in amounts consistent with CGMP.

III. Conclusion

The agency has completed its evaluation of the objections and concludes, for the reasons discussed in this document, that the objection to the specifications does not require any change in the regulation listing D&C Yellow No. 10 as a color additive. FDA also concludes that the objections to the limitations on the use of D&C Yellow No. 10 in drugs and cosmetics are correct, and the agency is modifying the final rule accordingly. No requests for a hearing were received in response to the listing regulation. Therefore, this document terminates the stay of the regulation and confirms the effective date of September 30, 1983, for all portions of the final rule. No further issue may be taken with regard to any provisions of the August 30, 1983 final rule, except as discussed below.

The agency, however, will apply the specifications for D&C Yellow No. 10 established in §§ 74.1710 and 74.2710 only prospectively from March 7, 1984, rather than retroactively from September 30, 1983. The specification requirements in the provisional listing regulations, which were different than those in the listing regulations, remained in effect until the publication of this document and thus were the appropriate standard to judge those batches of D&C Yellow No. 10 that the agency considered for certification between the publication of the final rule and the publication of this document. Nonetheless, with the publication of this document, any batches of D&C Yellow No. 10 that were not certified by the agency by March 7, 1984, will be considered for certification under the standards established in §§ 74.1710 (a) and (b) and 74.2710(a).

Objections to or requests for a public hearing on the modifications in §§ 74.1710(c) and 74.2710(b) set forth in this document may be submitted under §§ 12.20 through 12.22 (21 CFR 12.20 through 12.22). The agency will publish a final rule confirming the effective date for the amended portion (uses and restrictions) of the regulations after the agency has had an opportunity to receive and to act on any objections to the modifications. The amended portions of these regulations (§§ 74.1710(c) and 74.2710(b)) shall become effective on April 9, 1984, except as to any provisions that may be stayed by the filing of proper objections. Until that time, the uses and restrictions prescribed by the listing regulation of August 30, 1983 (48 FR 39217), are in effect.

With the confirmation of the effective date for the regulations listing D&C Yellow No. 10, continued provisional listing will no longer be appropriate or necessary. Accordingly, the agency is removing those parts of the regulations that pertain to the provisional listing of this color additive, i.e., §§ 81.1(b), 81.25, and 81.27.

List of Subjects

21 CFR Part 74

Color additives, Color additives subject to certification, Cosmetics, Drugs.

21 CFR Part 81

Color additives, Color additives provisional list, Cosmetics, Drugs.

21 CFR Part 82

Color additives, Color additives lakes, Color additives provisional list, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706 (b), (c), and (d), 52 Stat. 1055–1056 as amended, 74 Stat. 399–403 as amended (21 U.S.C. 371, 376 (b), (c), and (d))) and the transitional provisions of the Color

Additive Amendments of 1960 (Title II, Pub. L. 86-618, sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), the stay of effectiveness of § 74.1710; § 74.2710; and § 82.1710 is terminated and the effective date is now September 30, 1983. In addition, Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. Part 74 is amended:

a. By revising § 74.1710(c) to read as follows:

§ 74.1710 D&C Yellow No. 10.

* * * * *

(c) *Uses and restrictions.* The color additive D&C Yellow No. 10 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

* * * * *

b. By revising § 74.2710(b) to read as follows:

§ 74.2710 D&C Yellow No. 10.

* * * * *

(b) *Uses and restrictions.* The color additive D&C Yellow No. 10 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

* * * * *

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

2. Part 81 is amended:

§ 81.1 [Amended]

a. In § 81.1 *Provisional lists of color additives* by removing the entry for "D&C Yellow No. 10" from the table in paragraph (b).

§ 81.25 [Amended]

b. In § 81.25 *Temporary tolerances* by removing the entries for "D&C Yellow No. 10" from paragraphs (a)(1), (b)(1)(i), and (c)(1).

§ 81.27 [Amended]

c. In § 81.27 *Conditions of provisional listing* by removing the entry for "D&C Yellow No. 10" from the table in paragraph (d).

Any person who will be adversely affected by the amendments to §§ 74.1710(c) and 74.2710(b) may at any time on or before April 6, 1984, file with the Dockets Management Branch (address above) written objections thereto. Objections shall show how the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issue for the hearing and shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Three copies of all documents shall be filed and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. September 30, 1983, except that the modifications of §§ 74.1710(c) and 74.2710(b) announced in this document shall become effective April 9, 1984, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the **Federal Register.**

(Secs. 701, 706 (b), (c), and (d), 52 Stat. 1055-1056 as amended, 74 Stat. 399-403 as amended (21 U.S.C. 371, 376 (b), (c), and (d); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note))

Dated: March 2, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-6183 Filed 3-5-84; 10:56 am]

BILLING CODE 4160-01-M

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21 CFR Part 178

[Docket No. 82F-0156]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Octyltin Stabilizers in Vinyl Chloride Plastics; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that amended the food additive regulations to provide for the safe use of C_{10-16}-alkyl mercaptoacetates reaction products with dichlorodioctylstannane and trichlorooctylstannane as a stabilizer for vinyl chloride plastics intended for use in contact with food. This document corrects the Chemical Abstracts Registry number.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: In FR Doc. 83-4190 appearing at page 7169 in the issue for Friday, February 18, 1983, the following correction is made on page 7170: In the second column under § 178.2650 *Octyltin stabilizers in vinyl chloride plastics* in the fifth line of paragraph (a)(3), the CAS Reg. No. now reading "83947-69-2" is corrected to read "83447-69-2".

Dated: March 1, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-6054 Filed 3-6-84; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject To Certification; Fenbendazole Paste

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by American Hoechst Corp., providing for safe and effective use of fenbendazole paste as an anthelmintic in cattle.

EFFECTIVE DATE: March 7, 1984.

FOR FURTHER INFORMATION CONTACT: Adriano R. Gabuten, Bureau of Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: American Hoechst Corp., Animal Health Division, Route 202-206 North, Somerville, NJ 08876, is sponsor of NADA 132-872, providing for use of fenbendazole paste 10 percent. The paste is for oral use in cattle for removal and control of lungworm (*Dictyocaulus viviparus*), barberpole worm (*Haemonchus contortus*), brown stomach worm (*Ostertagia ostertagi*), small stomach worm (*Trichostrongylus axei*), hookworm (*Bunostomum phlebotomum*), thread-necked intestinal worm (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), and