

Under the transitional provision of the Amendments (section 203(a)(2)), the Commissioner may "terminate the postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement."

The Commissioner finds that there has been a failure to comply with the conditions attached to the postponement of the closing date and hereby terminates the postponement of the closing date for the provisional listing of Ext. D&C Green No. 1 for use in externally applied drugs and cosmetics in accordance with section 203(a)(2) of the transitional provisions of the Color Additive Amendments of 1960. It is not possible to certify batches of the color without adequate analytical methods and data. Because the petitioner has not complied with the requirements of § 81.27(c)(2) (21 CFR 81.27(c)(2)) and in the absence of the required data that are considered to be necessary for certification of the color, the Commissioner concludes that the provisional listing of Ext. D&C Green No. 1 shall be terminated on November 29, 1977. Published elsewhere in this issue of the *FEDERAL REGISTER* is a notice denying the petition to list the color additive for use in externally applied drugs and cosmetics.

All certificates heretofore issued for batches of Ext. D&C Green No. 1 are revoked and the addition of the color to externally applied drugs or cosmetics after November 29, 1977 will cause such product to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and subject to regulatory action. This prohibition applies to the use of the straight color, its lakes, and mixtures of Ext. D&C Green No. 1 or its lake. The Commissioner concludes that the protection of the public health does not require the recall from the market of drugs and cosmetics containing the color additive, or the destruction of drugs or cosmetics in preparation to which the color additive has already been added.

Manufacturers of new drugs and new animal drugs (including certifiable antibiotics for animal use) that contain Ext. D&C Green No. 1 may either delete the color additive or substitute a different color in accordance with the provisions of § 314.8 (d)(3) and (e) or § 314.8 (d)(3) and (e) (21 CFR 314.8 (d)(3) and (e) or 21 CFR 314.8 (d)(3) and (e)) as appropriate. The applicant shall submit data providing the new composition and showing that the change in composition does not interfere with any assay or other control procedures used in manufacturing the drug, or that the assay and control procedures used in manufacturing the drug have been revised to make them adequate. The applicant shall also submit data available to establish the stability of the revised

formulation or, if the data are too limited to support a conclusion that the drug will retain its declared potency for a reasonable marketing period, a commitment to test the stability of marketed batches at reasonable intervals, to submit the data as they become available, and to recall from the market any batch found to fall outside the approved specifications for the drug.

Each sponsor of a notice of claimed investigational exemption for a new drug (IND) or a notice of claimed investigational exemption for a new animal drug (INAD) containing the subject color should promptly amend the IND or INAD to indicate that the color additive has been deleted or a different color additive substituted.

The Commissioner is aware that supplies of alternative color additives may be difficult to obtain immediately. Consequently, drug and cosmetic labeling that states that the product contains "artificial color," or that specifically identifies Ext. D&C Green No. 1, may continue to be used with the uncolored product or products containing alternative colors during the time necessary to obtain supplies of revised labeling or until November 29, 1978, whichever occurs first.

The Commissioner has carefully considered the environmental effects of this action, and because the action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the FDA environmental assessment, together with copies of the other documents mentioned above, are on file with the Hearing Clerk (HFC-20), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Therefore, under 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 (21 CFR 5.1), Parts 81 and 82 are amended as follows:

1. Part 81 is amended:

§ 81.1 [Amended]

a. In § 81.1 *Provisional lists of color additives*, in paragraph (c), by deleting the table entry for Ext. D&C Green No. 1.

b. In § 81.10 by adding new paragraph (k), to read as follows:

§ 81.10 Termination of provisional listing of color additives.

(k) *Ext. D&C Green No. 1.* The Commissioner concludes that there are inadequate analytical methods to permit certification of the color additive Ext. D&C Green No. 1. In addition, the Commissioner has found that there was a failure to comply with the conditions attached to the postponement of the closing date in accordance with section 203(a)(2) of the transitional provisions of the Color Additive Amendments of 1960. The Commissioner of Food and Drugs hereby terminates the provisional listing of Ext. D&C Green No. 1 for use in externally applied drugs and cosmetics, effective November 29, 1977.

c. In § 81.30 paragraphs (k) and (l) are reserved and new paragraph (m) is added to read as follows:

§ 81.30 Cancellation of certificates.

(k)-(l) [Reserved]

(m) (1) Certificates issued for Ext. D&C Green No. 1 and all mixtures containing this color additive are cancelled and have no effect after November 29, 1977, and use of the color additive in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

§ 82.2201 [Revoked]

2. Part 82 is amended by revoking § 82.2201 *Ext. D&C Green No. 1.*

Notice and public procedure are not necessary prerequisites to the promulgation of this order because section 203 (d)(2) of Pub. L. 86-618 so provides.

Effective date: November 29, 1977.

(Sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note).)

Dated: November 21, 1977.

JOSEPH P. HILE,
Associate Commissioner
for Compliance.

[FR Doc. 77-34038 Filed 11-28-77; 8:45 am]

[4110-03]

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 75N-0249]

PART 314—NEW DRUG APPLICATIONS

Procedures for Filing Over Protest

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This amendment revises the agency's regulation governing the procedure for filing a new drug application (NDA) over protest. It extends from 60 to 90 days the time within which FDA must respond to a request to file over protest, and it specifies that such requests should be submitted to the Assistant Director for Regulatory Affairs, Bureau of Drugs.

EFFECTIVE DATE: December 29, 1977.

ADDRESS: Requests for a new drug application (NDA) or abbreviated new drug application (ANDAs) to be filed over protest should be sent to the Assistant Director for Regulatory Affairs (HFD-30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Jean Mansur, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3640.

SUPPLEMENTARY INFORMATION: In the *FEDERAL REGISTER* of September 26, 1975 (40 FR 44335), the Commissioner of Food and Drugs proposed to revise § 314.110(d) (21 CFR 314.110(d)) in two respects: first, to extend the time within which FDA must respond to a request to file an NDA or ANDA over protest from 60 to 90 days; and second, to specify that such requests should be submitted to the office of the Hearing Clerk, Food and Drug Administration. Interested persons were given 60 days to comment on the proposal.

Section 314.110(d) sets forth a procedure whereby an applicant who disputes the finding by FDA that his NDA may not be filed because it is incomplete or inadequate may make a written request that the NDA be filed over protest. This request, which an applicant submits instead of additional information of the kind specified by FDA, represents his contention that the application is complete and adequate and that no further data are required for its approval. The agency then reevaluates the NDA and either approves it or gives the applicant notice of an opportunity for a hearing on the question of whether it is approvable. A request that an NDA be filed over protest, like other correspondence pertaining to an NDA, is now usually submitted directly to the division in the Bureau of Drugs that is responsible for review of the NDA.

Eight comments on the proposal were received. The comments came from drug firms, professional associations, and an individual. A summary of the comments and the Commissioner's conclusions are as follows.

1. Five comments objected to the provision that would require a request to file an NDA over protest be submitted to the Hearing Clerk, Food and Drug Administration instead of the Bureau of Drugs. The comments said such a change would make the existence of a pending NDA public information when previously this has been considered proprietary information and, as a consequence, has been kept confidential. The comments acknowledged that a request to file an NDA over protest could result in publication of a notice of opportunity for hearing, making the existence of an application public information at that point, but argued there is no reason to make such information public any earlier than is necessary. Early disclosure, they said, could be a potential advantage to competitors.

The preamble to the proposal explained that the reason for specifying that a request to file an NDA over protest be submitted to the Hearing Clerk was to assure processing of such requests within the time limits specified in the regulations. It was believed that the use of a single office responsible for their receipt and monitoring would serve to highlight these requests as high priority submissions and preclude their being obscured by the many routine, pending NDA submissions. The Commissioner acknowledged in the preamble that sub-

missions to the office of the Hearing Clerk would result in public disclosure of a pending NDA somewhat before this information normally is disclosed by publication in the *FEDERAL REGISTER* of a notice of opportunity for hearing or by public notice that the application is the subject of an approvable letter.

After considering the comments on this question, the Commissioner has decided to modify the proposed change to provide that requests to file an NDA over protest be submitted to the Assistant Director for Regulatory Affairs, Bureau of Drugs (address given above). The Commissioner expects that designating a place for receipt of these requests other than the office of the Hearing Clerk or the reviewing division will accomplish his intended purpose. It will assist the Bureau in expeditiously handling them. At the same time it will not make public the existence of a pending NDA any sooner than would occur under present practice.

2. One comment agreed that extending the time from 60 to 90 days for FDA to evaluate an NDA that is the subject of a request to file over protest is reasonable. Four comments expressed the view that the extension of time is unreasonable and unnecessary. They contended that 60 days is a sufficient time for approval or issuance of a notice of opportunity for a hearing because the application will have been thoroughly reviewed recently and because the overall process of NDA review and resolution of conflicts as to approvability already requires a substantial amount of time. One comment said that in almost all instances where an applicant requests filing over protest, it is because of minor technical inadequacies that are clear from a cursory examination and can be corrected relatively easily in a resubmission of the NDA. Another of these comments offered a counterproposal—that if an applicant sends his request to file over protest within 30 days after being notified of the agency's refusal to file, FDA should likewise have only 30 days to respond; otherwise, FDA could use up to 90 days. Another comment suggested that if FDA performed a cursory initial examination of the application and within 30 days notified the applicant of its deficiencies, then a much longer period would be justified for detailed review if the applicant requested filing over protest; but, it continued, where the initial review is comprehensive and time-consuming, the applicant is entitled to a rapid response upon filing over protest. One of the comments further said that even if a drug is improvidently approved, it can be recalled without a prior hearing if it creates an imminent health hazard. This same comment proposed that FDA be allowed 90 days to respond only if the applicant agrees or if FDA certifies to the applicant that there is more than a mere possibility that the FDA will find, without submission of further data, that the drug for which approval is sought is safe and effective.

The Commissioner disagrees with those comments opposing the extension of time. Under § 314.110, an NDA filed over protest must be approved or must be the subject of a notice of opportunity for hearing on the issue of its approvability. Unless the application is grossly deficient, a cursory examination that does not reveal all inadequacies of an NDA is not a satisfactory basis for initially refusing to file when such action may result in filing the application over protest. In addition, this would be likely to introduce another step in the review process: An applicant who responded to the cursory initial examination by furnishing more information for his NDA might very likely be notified of other deficiencies when a more comprehensive review was undertaken. Such a "piecemeal" approach has traditionally met with disfavor on the part of the drug industry.

The current approach of FDA is to have the responsible division review the NDA or ANDA in sufficient depth that at least all major problems can be identified. In cases where an apparently insurmountable single problem is immediately found, however, other, more technical reviews may be postponed until the single problem is remedied or the application is filed over protest and a hearing is requested. In any event, the decision not to accept an NDA for filing is delegated to FDA's division directors who can, do, and must rely on the act, regulations, general policies and specific precedents in making the decisions. They may consult with superiors, other Bureau or FDA officials, or the Office of Chief Counsel for guidance, but this is not required.

However, when an NDA is filed over protest, the reasons for rejecting the NDA and the underlying approvability or nonapprovability issues are reviewed throughout the Bureau (and with the Office of Chief Counsel). The procedure may include the following: evaluation by medical officers, pharmacologists, microbiologists, and chemists, as appropriate, depending on the issues; possible consultation with experts, advisory committees, FDA laboratory personnel; supervisory, administrative, and legal reviews appropriate to an institutional decision; and preparation of either the approval letter or the notice of opportunity for hearing, with publication of the latter in the *FEDERAL REGISTER*.

This description of the practice within FDA should make it clear why it is in the interest of the applicant, the FDA, and the public that adequate time be allowed for reasonable internal reevaluation of the NDA rather than, in effect, requiring mere reiteration of the rejection for filing. Experience has shown that in some instances, the reevaluation has led to a resolution of the problems without a formal hearing, or to a clarification of policy that eliminated the need for a hearing, or to other actions that avoided prolonged and unnecessary legal maneuvering.

The fact that approval of an NDA may be withdrawn without a prior hearing if it creates an imminent health hazard does not justify approving it in the first instance if the NDA is incomplete or inadequate in the data required to demonstrate safety and effectiveness and the adequacy of manufacturing procedures.

Since the amendment to § 314.110(d) was proposed, FDA has received at least 16 requests to file NDAs over protest. New drug applications that reach this stage may present issues that are complex and may involve voluminous or technical material. Each of these factors has reemphasized the need for more than 60 days for agency response. The change to allow 90 days will make the regulations more realistic.

3. One comment said the 90-day limit should be extended to include new animal drugs under § 514.110 (21 CFR 514.110), where no time limit currently exists.

The Commissioner is considering this suggestion. If he concludes that such a change in the new animal drug regulations is warranted, it will be the subject of a future FEDERAL REGISTER notice.

4. One comment proposed that a second notice and comment period be added to the rulemaking process.

The Commissioner finds that the current procedures for interested persons to comment on proposed amendments to the regulations are sufficient, and any additional period for submitting comments would needlessly prolong the rulemaking process without providing any significant public benefit.

5. The Commissioner also provides the following information: A request that an NDA be filed over protest is an option set forth in the regulatory scheme applicable to new drug procedures (21 CFR Part 314) that an applicant may choose instead of the option of amending the application by submitting more data in response to the stated deficiencies. Although this has been generally understood within the drug industry, there have been instances in which an applicant both submitted data to amend the NDA and requested that the NDA be filed over protest. This points out the need to clarify § 314.110(d) to show that these are alternative options. Although not included in the proposal, this clarifying language is included in this regulation.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355)) and under authority delegated to the Commissioner (21 CFR 5.1), § 314.110 is amended by revising paragraph (d) and adding new paragraph (e), to read as follows:

§ 314.110 Reasons for refusing to file applications.

(d) If an applicant disputes the finding that his application is incomplete or inadequate and, therefore, may not be filed, he may, instead of submitting additional data, make written request that the previously submitted application be filed over protest. Such request shall be sub-

mitted to the Assistant Director for Regulatory Affairs (HFD-30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

(e) Upon receipt of a written request to file an application over protest, the Food and Drug Administration shall consider the application filed and shall reevaluate the application. Within 90 days of the date of receipt of such written request by the Assistant Director for Regulatory Affairs, or such additional period as may be agreed upon by the parties, the application shall be approved, or the applicant shall be given hearing pursuant to § 314.200 on the written notice of an opportunity for a question of whether there are grounds for denying approval pursuant to section 505(d) of the act.

Effective date: This regulation shall be effective December 29, 1977.

(Sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355).)

NOTE.—The Commissioner has considered the economic impact of the regulation and no major economic impact has been found, as defined in Executive Order 11821, as amended by Executive Order 11949, OMB Circular A-107, and guidelines issued by the Department of Health, Education, and Welfare. Copies of the economic impact assessment are on file with the Hearing Clerk, Food and Drug Administration.

Dated: November 21, 1977.

JOSEPH P. HILE,
Associate Commissioner
for Compliance.

[FR Doc.77-34039 Filed 11-28-77;8:45 am]

[7550-01]

Title 29—Labor

CHAPTER X—NATIONAL MEDIATION BOARD

PART 1209—PUBLIC OBSERVATION OF NATIONAL MEDIATION BOARD MEETINGS

AGENCY: National Mediation Board.

ACTION: Notice of Interim Rulemaking.

SUMMARY: The interim regulations replace Section 1209 of the National Mediation Board Rules. The interim regulations allow the Board to utilize the expedited procedures of the Sunshine Act to close deliberations exempt from public observation and qualifying for closure by expedited procedures. The interim regulations continue to provide for closure by regular procedures of other deliberations exempt from public observation.

DATES: Effective on an interim basis on November 29, 1977. Written comments received on or before December 29, 1977.

ADDRESS: Written comments should be addressed to Mr. Rowland K. Quinn, Jr., Executive Secretary, National Mediation Board, Washington, D.C. 20572.

FOR FURTHER INFORMATION CONTACT:

Rowland K. Quinn, Jr., Executive Secretary, National Mediation Board, Telephone 202-523-5920.

SUPPLEMENTARY INFORMATION: These interim regulations are issued pursuant to the authority of 5 U.S.C. 552b (g) and 44 Stat. 577, as amended (45 U.S.C. 151 et seq.).

By direction of the National Mediation Board.

Dated: November 22, 1977.

ROWLAND K. QUINN, JR.,
Executive Secretary.

29 CFR, Chapter X, is amended by substitution of the following for the existing Part 1209:

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| Sec. | |
| 1209.01 | Scope and purpose. |
| 1209.02 | Definitions. |
| 1209.03 | Conduct of National Mediation Board business. |
| 1209.04 | Open meetings. |
| 1209.05 | Closing of meetings; reasons therefor. |
| 1209.06 | Action necessary to close meetings; record of votes. |
| 1209.07 | Notice of meetings; public announcement and publication. |
| 1209.08 | Transcripts, recordings or minutes of closed meetings; retention; public availability. |
| 1209.09 | Requests for records under Freedom of Information Act. |
| 1209.10 | Capacity of public observers. |

AUTHORITY: 5 U.S.C. 552b(g), 44 Stat. 577, as amended (45 U.S.C. 151 et seq.).

§ 1209.01 Scope and purpose.

(a) The provisions of this part are intended to implement the requirements of section 3(a) of the Government in the Sunshine Act, 5 U.S.C. 552b.

(b) It is the policy of the National Mediation Board that the public is entitled to the fullest practicable information regarding its decisionmaking processes. It is the purpose of this part to provide the public with such information while protecting the rights of individuals and the ability of the agency to carry out its responsibilities.

§ 1209.02 Definitions.

For purposes of this part:

(a) The terms "Board" or "agency" mean the National Mediation Board, a collegial body composed of three members appointed by the President with the advice and consent of the Senate.

(b) The term "meeting" means the deliberations of at least two members of the Board where such deliberations determine or result in the joint conduct or disposition of official agency business, but does not include deliberations required or permitted or with respect to any information proposed to be withheld under by 5 U.S.C. 552b(d) or (e) / 5 U.S.C. 552b(c).

§ 1209.03 Conduct of National Mediation Board business.

Members shall not jointly conduct or dispose of agency business other than in accordance with this part.

§ 1209.04 Open meetings.

Every portion of every Board meeting shall be open to public observation, except as otherwise provided by § 1209.05 of this Part.

§ 1209.05 Closing of meetings; reasons therefor.

(a) Except where the Board determines that the public interest requires otherwise, meetings, or portions thereof, shall not be open to public observation where the deliberations concern the issuance of a subpoena, the Board's participation in a civil action or proceeding or an arbitration, or the initiation, conduct or disposition by the Board of any matter involving a determination on the record after opportunity for a hearing, or any court proceedings collateral or ancillary thereto.

(b) Except where the Board determines that the public interest requires otherwise, the Board also may close meetings, or portions thereof, when the deliberations concern matters or information falling within the scope of 5 U.S.C. 552b (c) (1) (secret matters concerning national defense or foreign policy); (c) (2) (internal personnel rules and practices); (c) (3) (matters specifically exempted from disclosure by statute); (c) (4) (trade secrets and commercial or financial information obtained from a person and privileged or confidential); (c) (5) (matters of alleged criminal conduct or formal censure); (c) (6) (personal information where disclosure would cause a clearly unwarranted invasion of personal privacy); (c) (7) (certain materials or information from investigatory files compiled for law enforcement purposes); or (c) (9) (B) (disclosure would significantly frustrate implementation of a proposed agency action).

§ 1209.06 Action necessary to close meetings; record of votes.

A meeting shall be closed to public observation under § 1209.05, only when a majority of the members of the Board who will participate in the meeting vote to take such action.

(a) When the meeting deliberations concern matters specified in § 1209.05(a), the Board members shall vote at the beginning of the meeting, or portion thereof, on whether to close such meeting, or portion thereof, to public observation, and on whether the public interest requires that a meeting which may properly be closed should nevertheless be open to public observation. A record of such vote, reflecting the vote of each member of the Board, shall be kept and made available to the public at the earliest practicable time.

(b) When the meeting deliberations concern matters specified in § 1209.05(b), the Board shall vote on whether to close such meeting, or portion thereof, to public observation, and on whether the public interest requires that a meeting which may properly be closed should nevertheless be open to public observation. The vote shall be taken at a time sufficient to permit inclusion of information concerning the open or closed status of the meeting in the public announcement thereof. A single vote may be taken with respect to a series of meetings at which the deliberations will concern the same particular matters where subsequent meetings in the series are scheduled

to be held within thirty days after the initial meeting. A record of such vote, reflecting the vote of each member of the Board, shall be kept and made available to the public within one day after the vote is taken.

(c) Whenever any person whose interests may be directly affected by deliberations during a meeting, or a portion thereof, requests that the Board close that meeting, or portion thereof, to public observation for any of the reasons specified in 5 U.S.C. 552b(c) (5) (matters of alleged criminal conduct or formal censure), (c) (6) (personal information where disclosure would cause a clearly unwarranted invasion of personal privacy), or (c) (7) (certain materials or information from investigatory files compiled for law enforcement purposes), the Board members participating in the meeting, upon request of any one member of the Board, shall vote on whether to close such meeting, or a portion thereof, for that reason. A record of such vote, reflecting the vote of each member of the Board participating in the meeting, shall be kept and made available to the public within one day after the vote is taken.

(d) After public announcement of a meeting as provided in § 1209.07 of this part, a meeting, or portion thereof, announced as closed may be opened or a meeting, or portion thereof, announced as open may be closed, only if a majority of the members of the Board who will participate in the meeting determine by a recorded vote that Board business so requires and that an earlier announcement of the change was not possible. The change made and the vote of each member on the change shall be announced publicly at the earliest practicable time.

(e) Before a meeting may be closed pursuant to § 1209.05 the General Counsel of the Board shall certify that in his or her opinion the meeting may properly be closed to public observation. The certification shall set forth each applicable exemptive provision for such closing. The certification shall be retained by the agency and made publicly available as soon as practicable.

§ 1209.07 Notice of meetings; public announcement and publication.

(a) A public announcement setting forth the time, place and subject matter of meetings or portions thereof closed to public observation pursuant to the provisions of § 1209.05(a) of this part, shall be made at the earliest practicable time.

(b) Except for meetings closed to public observation pursuant to the provisions of § 1209.05(a) of this part, the agency shall make public announcement of each meeting at least 7 days before the scheduled date of the meeting. The announcement shall specify the time, place and subject matter of the meeting, whether it is to be open to public observation or closed, and the name, address and phone number of an agency official designated to respond to requests for information about the meeting. The 7 day period for advance notice may be shortened only upon a determination by a majority of the members of the Board who will participate in the meeting that

agency business requires that such meeting be called at an earlier date, in which event the public announcement shall be made at the earliest practicable time. A record of the vote to schedule a meeting at an earlier date shall be kept and made available to the public.

(c) Within one day after a vote to close a meeting, or any portion thereof, pursuant to the provisions of § 1209.05(b) of this part, the agency shall make publicly available a full written explanation of its action closing the meeting, or portion thereof, together with a list of all persons expected to attend the meeting and their affiliation.

(d) If after a public announcement required by paragraph (b) of this section has been made, the time and place of the meeting are changed, a public announcement of such changes shall be made at the earliest practicable time. The subject matter of the meeting may be changed after public announcement thereof only if a majority of the members of the Board who will participate in the meeting determine that agency business so requires and that no earlier announcement of the change was possible. When such a change in subject matter is approved a public announcement of the change shall be made at the earliest practicable time. A record of the vote to change the subject matter of the meeting shall be kept and made available to the public.

(e) All announcements or changes thereof issued pursuant to the provisions of paragraphs (b) and (d) of this section, or pursuant to the provisions of § 1209.06(d), shall be submitted for publication in the FEDERAL REGISTER immediately following their release to the public.

(f) Announcement of meetings made pursuant to the provisions of this section shall be posted on a bulletin board maintained for such purpose at the Board's offices, 1425 K Street, N.W., Washington, D.C. Interested individuals or organizations may request the Executive Secretary, National Mediation Board, Washington, D.C. 20572 to place them on a mailing list for receipt of such announcements.

§ 1209.08 Transcripts, recordings or minutes of closed meetings; retention; public availability.

(a) For every meeting or portion thereof closed under the provisions of § 1209.05, the presiding officer shall prepare a statement setting forth the time and place of the meeting and the persons present, which statement shall be retained by the agency. For each such meeting or portion thereof there also shall be maintained a complete transcript or electronic recording of the proceedings, except that for meetings closed pursuant to § 1209.05(a) the Board may, in lieu of a transcript or electronic recording, maintain a set of minutes fully and accurately summarizing any action taken, the reason therefor and views thereof, documents considered, and the members' vote on each roll call vote.

(b) The agency shall maintain a complete verbatim transcript, a complete electronic recording, or a complete set

of minutes for each meeting or portion thereof closed to public observation, for a period of at least one year after the close of the agency proceeding of which the meeting was a part, but in no event for a period less than two years after such meeting.

(c) The agency shall make promptly available to the public copies of transcripts, electronic recordings or minutes maintained as provided in paragraphs (a) and (b) of this section, except to the extent the items therein contain information which the agency determines may be withheld pursuant to the provisions of 5 U.S.C. 552b(c).

(d) Upon request in accordance with the provisions of this paragraph and except to the extent they contain information which the agency determines may be withheld pursuant to the provisions of 5 U.S.C. 552b(c), copies of transcripts or minutes, or transcriptions of electronic recordings including the identification of speakers, shall be furnished subject to the payment of duplication costs in accordance with the schedule of fees set forth in § 1208.06 of the Board's Rules, and the actual cost of transcription. Requests for copies of transcripts or minutes, or transcriptions of electronic recordings of Board meetings shall be directed to the Executive Secretary, National Mediation Board, Washington, D.C. 20572. Such requests shall reasonably identify the records sought and include a statement that whatever costs are involved in furnishing the records will be acceptable or, alternatively, that costs will be acceptable up to a specified amount. The Board may determine to require prepayment of such costs.

§ 1209.09 Requests for records under Freedom of Information Act.

Requests to review or obtain copies of agency records other than notices or records prepared under this part may be pursued in accordance with the Freedom of Information Act (5 U.S.C. 552). Part 1208 of the Board's Rules addresses the requisite procedures under that Act.

§ 1209.10 Capacity of public observers.

The public may attend open Board meetings for the sole purpose of observation. Observers may not participate in meetings unless expressly invited or otherwise interfere with the conduct and disposition of agency business. When a portion of a meeting is closed to the public, observers will leave the meeting room upon request to enable discussion of the exempt matter therein under consideration.

[FR Doc.77-34180 Filed 11-28-77;8:45 am]

[4810-25]

**Title 31—Money and Finance: Treasury
SUBTITLE A—OFFICE OF THE SECRETARY
OF THE TREASURY**

**PART 4—EMPLOYEES' PERSONAL
PROPERTY CLAIMS**

Maximum Dollar Limit

AGENCY: Department of the Treasury.

ACTION: Final rule.

SUMMARY: To amend the Treasury Department's regulations at 31 CFR Part 4, "Employees' Personal Property Claims," by raising the maximum dollar limit the Department may pay in settlement of an employee's claim to conform with the Military and Civilian Employees Act of 1964, 31 U.S.C. 241-243, as amended by Section 1(a) of Pub. L. 93-455, October 18, 1974. The 1974 amendment raised the limit to \$15,000.

EFFECTIVE DATE: November 29, 1977.

FOR FURTHER INFORMATION CONTACT:

Ronald Levy, Attorney-Adviser, Office of the General Counsel, Department of the Treasury, Washington, D.C. 20220, telephone 202-566-2327.

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. 553(b) the Department finds that notice and public procedure are unnecessary as the regulations are being amended solely to conform with law.

Accordingly, Title 31 § 4.1 of the Code of Federal Regulations is amended by deleting "\$6,500" and by inserting "\$15,000" in lieu thereof.

WILLIAM J. BECKHAM, JR.,
Assistant Secretary,
Administration.

NOVEMBER 22, 1977.

[FR Doc.77-34171 Filed 11-28-77;8:45 am]

[6560-01]

Title 40—Protection of Environment

**CHAPTER I—ENVIRONMENTAL
PROTECTION AGENCY**

[FRL 821-8]

**PART 205—NOISE EMISSION STANDARDS
FOR MEDIUM AND HEAVY TRUCKS**

Interim Warranty

AGENCY: Environmental Protection Agency.

ACTION: Interim Noise Emissions Warranty for Medium and Heavy Trucks.

SUMMARY: This notice is intended to notify all medium and heavy duty truck manufacturers of the Agency's determination that subject to the conditions set forth in the letter, manufacturers may offer the alternate warranty for incomplete vehicles pending final judicial resolution of the warranty issue.

EFFECTIVE DATE: November 29, 1977.

FOR FURTHER INFORMATION CONTACT:

Richard G. Kozlowski, Director, Noise Enforcement Division (EN-387), U.S. Environmental Protection Agency, Washington, D.C. 20460, 703-557-7470.

SUPPLEMENTARY INFORMATION: Copies of the letter presented below have been sent to all vehicle manufacturers subject to 40 CFR Part 205, Subpart B, Transportation Equipment Noise Emission Controls, Medium and Heavy Trucks ("the truck regulation"). The

letter arose out of discussions with counsel for General Motors Corporation and International Harvester Company, parties to the ongoing litigation over the truck regulation. The letter sets forth an alternate warranty that may be used for incomplete vehicles on an interim basis by vehicle manufacturers subject to the truck regulation.

All vehicle manufacturers subject to the truck regulation may use the alternate warranty subject to the conditions set forth in the letter. Use of the alternate warranty constitutes acceptance of the conditions set forth in the letter.

The letter:

The Environmental Protection Agency has determined that, subject to the conditions set forth below, the attached language ("the alternate warranty") may be used for incomplete vehicles on an interim basis by vehicle manufacturers subject to the requirements of 40 CFR Part 205, Subpart B, to meet the requirement of the "Noise Emissions Warranty" as set forth in 40 CFR § 205.58-1 ("the existing warranty").

This alternate warranty may be used only on an interim basis, i.e., until no more than sixty (60) days following final judicial resolution of the warranty issue raised by General Motors and International Harvester in *Chrysler Corp. et al. v. EPA* (C.A.D.C. No. 76-1569, 76-1575, 76-1576, 76-1582), and only subject to the following conditions:

The alternate warranty may only apply to incomplete vehicles, i.e., those vehicles which, after they leave the vehicle manufacturer's control, have further manufacturing operations, other than the addition of readily attachable components, applied to them before they are ready for commercial use. The existing warranty must apply to all other vehicles.

If final judicial resolution of the warranty issue raised in the aforementioned litigation substantially affirms the scope of the existing warranty, then it is the responsibility of the vehicle manufacturer to notify those purchasers to whom the alternate warranty was provided that the existing warranty applies retroactively; specifically, that all warranty claims will be honored as if the existing warranty had been supplied to the ultimate purchaser at the time of sale.

Dated: November 23, 1977.

MARVIN B. DURNING,
Assistant Administrator
for Enforcement.

**INCOMPLETE VEHICLE NOISE EMISSIONS
WARRANTY**

[Name of vehicle manufacturer] warrants to the first person who purchases this vehicle for purposes other than resale and to each subsequent purchaser that this vehicle, as manufactured by [name of vehicle manufacturer] was designed, built and equipped to conform at the time it left [name of vehicle manufacturer]'s control with all applicable U.S. EPA Noise Control Regulations.

This warranty covers this vehicle as designed, built and equipped by [name of vehicle manufacturer], and is not limited to any particular part, component or system of the vehicle manufactured by [name of vehicle manufacturer]. Defects in design assembly or in any part, component or system of the vehicle as manufactured by [name of vehicle manufacturer], which at the time it left [name of vehicle manufacturer]'s control, caused noise emissions to exceed Federal

standards, are covered by this warranty for the life of the vehicle.¹

[FR Doc. 77-34243 Filed 11-28-77; 8:45 am]

[4110-08]

Title 42—Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCA- TION, AND WELFARE

PART 35—HOSPITAL AND STATION MANAGEMENT

Subpart E—Contributions for the Benefit of Patients

AGENCY: Public Health Service, Department of Health, Education, and Welfare.

ACTION: Final rule.

SUMMARY: This rulemaking codifies hospital rules currently in practice in the Public Health Service. The language of Section 321 of the Public Health Service Act requires that rules concerning this section be made "pursuant to regulations." Section 321 provides, pursuant to regulations, for the control, management, and operation of all institutions, hospitals, and stations of the Service. Further, it provides that, pursuant to regulations, there will be care, treatment, and hospitalization of patients. The Public Health Service is often asked to accept contributions for the benefit of its patients from other patients, relatives of patients, employees, visitors, and the general public. These regulations govern the acceptance of such contributions, report of and accounting for contributions; define donors and acceptable contributions; and describe allowable expenditures of cash contributions.

EFFECTIVE DATE: These regulations are effective November 29, 1977.

FOR FURTHER INFORMATION CON- TACT:

Mr. Lowell Peart, Building 31, room 3B07, 9000 Rockville Pike, Bethesda, Md. 20014, 301-496-4606.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of April 1, 1977 (42 FR 17500-17501) the Public Health Service proposed rules on contributions for the benefit of patients. Previously the means by which various installations of the PHS handled such contributions was left largely to their discretion. Procedures were described by various internal administrative issuances. In reviewing a proposed change in such an internal directive at the National Institute of Health, the HEW Office of the General Counsel advised that Section 321 required such rules to be made pursuant to regulations.

Comments were invited on the proposed rules and one was received. The

commenter asked whether the term "station" means something different than "hospital". The term is included to maintain consistency with Section 321 of the Public Health Service Act which states "The Surgeon General, pursuant to regulations, shall—(a) Control, manage, and operate all institutions, hospitals, and stations of the Service * * * and to cover situations where there may be patients in a research station of the Service which is not connected with a hospital and is not an outpatient clinic. The commenter suggested that the paragraph on acceptance of contributions be reworded to make clear that the "officer in charge" refers to the person directly in charge of the hospital. The word "directly" will not be included because (1) this is inconsistent with the term "officer in charge" which is used uniformly throughout Part 35 and (2) its use may appear to set a limit on a matter of administrative delegation which is best left to the managers of individual PHS facilities. The commenter also called attention to two editorial errors. These have been corrected.

NOTE.—The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Dated: September 21, 1977.

JULIUS B. RICHMOND,
Assistant Secretary for Health.

Approved: November 21, 1977.

HALE CHAMPION,
Acting Secretary.

Accordingly, Part 35 of Title 42 of the Code of Federal Regulations is amended by adding the following new subpart E.

Subpart E—Contributions for the Benefit of Patients

- Sec. 35.61 Applicability.
- 35.62 Acceptance of contributions.
- 35.63 Report of and accounting for contributions.
- 35.64 Donors.
- 35.65 Acceptable personal property.
- 35.66 Expenditure of cash contributions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 835 (42 U.S.C. 216); sec. 321, 58 Stat. 695, as amended, 62 Stat. 1017 (42 U.S.C. 248).

Subpart E—Contributions for the Benefit of Patients

§ 35.61 Applicability.

This subpart sets forth the policies and procedures governing the acceptance and administration of contributions of money or property intended solely for the benefit of all patients in a ward or unit or a particular hospital or station of the Public Health Service, excluding outpatient clinics. Such contributions are distinguishable from (a) monies or other valuables belonging to specific patients which are accepted and held in custody for the convenience of the patient until such time as he or she wishes to withdraw them, and (b) gifts to the United States to support Public Health Service functions under section 501 of the Public

Health Service Act or other statutory provisions, which may be accepted and administered only in accordance with such statutory provisions or other applicable laws.

§ 35.62 Acceptance of contributions.

(a) The officer in charge of a hospital or station or his delegate may accept contributions of money or personal property which are donated for the general benefit of all patients within the hospital or station (or a ward or unit thereof) without further specification or conditions as to use. Contributions tendered subject to conditions by the donor, such as expenditure or use only on behalf of certain patients or for specific purposes, may not be accepted.

(b) Contribution of money or property shall be accepted in writing.

§ 35.63 Report of and accounting for contributions.

(a) Contributions of money accepted pursuant to § 35.62 (hereinafter referred to as "patient fund") will be treated consistently with Federal deposit rules and as supplemented with appropriate procedures of the facility. This regulation is not intended to exclude contributions for the benefit of patients from proper accountability and control of funds and property.

(b) Contributions of property accepted pursuant to § 35.62 shall be recorded and accounted for in the same manner as other property of a similar kind maintained in the hospital or station, but with suitable identification so that it can be distinguished from government-owned property.

§ 35.64 Donors.

Authorized contributions may be accepted from patients, employees and other individuals, and agencies and organizations.

§ 35.65 Acceptable personal property.

Contributions of personal property which may be accepted pursuant to § 35.62 include, but are not limited to, recreational equipment, furniture, radios and television sets. After its useful life, any cash proceeds realized upon disposition of such property shall be deposited to the credit of the patient fund and shall be available for expenditure pursuant to § 35.66(c).

§ 35.66 Expenditure of cash contribu- tions.

(a) Officials authorized to accept contributions shall not maintain control over the actual obligation or expenditure of such monies.

(b) Only those officers or employees specifically designated in writing by the officer in charge for such purpose may obligate and expend monies from the patient fund. The names of officials so designated shall be provided to the relevant fiscal control office.

(c) Subject to availability of sufficient funds, monies in the patient fund may be expended for materials, services or activities which contribute to the well-being or morale of patients, including but

¹ The scope of this warranty is currently the subject of litigation. The coverage of this warranty may be broadened to extend to the completed vehicle, whether or not completed by [name of vehicle manufacturer], or the warranty may otherwise be altered, depending upon the outcome of the litigation.