

the regulations. In order for them to be of maximum benefit, they must be made effective immediately.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure concerning these amendments are impracticable and unnecessary, and good cause is found for making these amendments effective less than 30 days after publication in the FEDERAL REGISTER.

The foregoing amendment shall become effective upon issuance. Done at Washington, D.C., this 14th day of December, 1977.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11621 and OMB Circular A-107.

R. I. BROWN,
Acting Deputy Administrator,
Veterinary Services.

[FR Doc. 77-36205 Filed 12-19-77; 8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS: GENERAL

[Docket No. 77N-0068]

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

New Drugs Containing Hexachlorophene

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule will amend drug regulations to prohibit marketing of certain hexachlorophene-containing new drugs. The prohibition will apply at the time the Director of the Bureau of Drugs issues a notice of opportunity for hearing on a proposal to refuse to approve a new drug application for such drug or on January 31, 1978, whichever comes first. This action is being taken because manufacturers of new drugs containing hexachlorophene have had approximately 5 years within which to submit adequate information upon which a new drug application can be approved.

EFFECTIVE DATE: January 19, 1978.

ADDRESSES: Written objections to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Paul O. Fehnel, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of April 19, 1977 (42 FR 20313), FDA proposed to amend

§ 250.250 (21 CFR 250.250) to prohibit the marketing of new drugs containing hexachlorophene for indications listed in § 250.250(c)(3) after a notice of opportunity for hearing is issued on a proposal by the Director of the Bureau of Drugs to refuse to approve such new drug application (NDA) or after September 30, 1977, whichever comes first. In response to the proposal, comments were received from three manufacturers and the Institute for Public Interest Representation. A summary of the significant comments and the Commissioner's conclusions are as follows:

1. One comment from a manufacturer of a drug product that contains hexachlorophene as a preservative assumed that the manufacturer's product was not covered by the proposal because of the small amount of hexachlorophene used and because it is used as a preservative only, but asked for clarification on this point.

The Commissioner advises that the April 19 proposal pertained only to NDA's for drug products that contain hexachlorophene as an active ingredient for use as a surgical scrub and for topical application as specified in § 250.250(c)(3)(i). It did not propose to change, nor does this final rule change, the provisions of § 250.250(c)(5) and (d), which indicate that the use of hexachlorophene as a preservative at a level not to exceed 0.1 percent will not in itself require the submission of an NDA. Hexachlorophene may be used only as part of a preservative system, however, and only where no other preservatives are available.

2. One comment suggested that the effective date be changed from September 30, 1977, to June 30, 1978. The comment argued that the extra time is needed to comply with FDA's requirements.

The Commissioner rejects this comment because it neither explains why the additional time is necessary to meet the FDA requirements, nor does it explain why the information could not have been submitted during the time that elapsed after the requirement for an NDA was published in the FEDERAL REGISTER of September 27, 1972 (37 FR 20160). Because the final regulation is being published later than expected, the proposed effective date of September 30, 1977 is being changed. The Commissioner is making the effective date 30 days after the date of publication in the FEDERAL REGISTER and is establishing January 31, 1978 as the date after which drug products containing hexachlorophene may not be marketed without an approval NDA.

3. One comment objected to the statement in the preamble of the proposal that manufacturers have had approximately 5 years within which to submit the necessary data in support of their NDA's. The comment said that a change in the efficacy guidelines was brought to the manufacturers' attention in July 1975 and contended that the reason some NDA's remain unapproved is because of the deficiencies in the review process, the

change in guidelines, and the difficulty in meeting arbitrarily set guidelines.

The "glove juice" test, i.e., the procedure used to determine the effectiveness of surgical scrubs, has since 1973 been part of the guidelines of the Division of Anti-infective Drug Products, Bureau of Drugs, for evaluating surgical scrubs. This test was adopted, with some modification, by the OTC Antimicrobial I Panel during its deliberations in 1973 and was published as part of the Panel's report in the FEDERAL REGISTER of September 13, 1974 (39 FR 33103). The OTC Antimicrobial I Panel was appointed by the Commissioner to review the data and information submitted to FDA and to prepare a report on the safety, effectiveness, and labeling of OTC products containing antimicrobial ingredients for topical human use. This test, therefore, has been in effect virtually from the time that NDA's have been required for hexachlorophene products.

With respect to the alleged deficiencies in the review process, all applications for surgical scrubs have been expeditiously reviewed by the Bureau of Drugs. Staff members of FDA have had numerous meetings with manufacturers to explain procedures, interpret conclusions, review statistical analyses, suggest changes in instructions for use of the product to improve its effectiveness, and explain the approval criteria. All applicants for NDA's for hexachlorophene-containing products have been required to conduct the same tests for specified label indications. Most of the NDA's submitted in response to the 1972 regulation have already been approved, which suggests that not all firms have found it difficult to meet the guidelines.

The Commissioner disagrees with the statement that the guidelines have been arbitrarily set, considering the nature of hexachlorophene surgical scrubs. Any product used as a surgical scrub should produce the highest possible reduction of microbial flora and should suppress the count in the surgical glove over a 6-hour period. If surgical scrubbing is going to be performed, the ideal product would remove all transient flora and reduce the resident flora to as low a level as possible. The product must also be acceptable to the user and not irritate the user's hands. It is widely recognized, however, that hexachlorophene scrubs do not produce a high initial reduction, but with constant repeated use will be effective in reducing resident flora and in suppressing the count in the user's glove during the wearing time. Because no alternative product giving high initial reduction and prolonged microbial suppression was marketed in 1972, at the time of the FDA action on hexachlorophene, the Panel recommended and the Commissioner agreed that hexachlorophene products should continue to be marketed as surgical scrubs and for handwashing as part of patient care. As products combining both attributes become available, the Commissioner believes that the criteria for evaluating a

surgical scrub product should be re-examined in the light of risk-benefit judgments.

4. One comment argued that the glove-juice test is not the proper test for hexachlorophene products because hexachlorophene is a bacteriostatic rather than a bactericidal agent. Further, it was contended that the 1-log reduction in bacterial count required by the glove-juice test is an arbitrary requirement. The comment said a proper test to determine the efficacy of a surgical scrub containing hexachlorophene would include the test product, a positive and a vehicle control, and studies in parallel in the same laboratory.

The definitions of bacteriostatic and bactericidal activity are not uniformly agreed upon. As the use of adequate neutralizers has been introduced into the testing procedures for antimicrobial chemicals, the ease with which the separation of these definitions is usually made has become significantly less. Acceptable kill curves and D-values have been required and determined for what have been generally accepted to be bactericidal and bacteriostatic chemical agents. It is obvious from historical data that a single scrub with a hexachlorophene-containing product does have an antimicrobial (bacteriostatic and/or bactericidal) effect on the skin microflora.

As stated in the response to comment 3 above, a product used as a surgical scrub should produce the highest possible reduction of microbial flora and suppress the count in the surgical glove over a 6-hour period. Therefore, any product that is used as a surgical scrub should meet a standard for initial reduction. The 1-log reduction referred to in the comment is therefore accepted as only the minimal level of reduction for a suitable surgical scrub in a handwashing test. In fact, this criterion can be met by some generally available antimicrobial bar soaps when tested under controlled conditions.

The glove-juice test is designed to test surgical scrubs formulated with chemicals of differing activity including, as part of the test, an objective assessment of initial reduction of microbial flora, action in suppressing growth of organisms while wearing the surgical glove, and the product's substantive activity. A substantive antimicrobial chemical is one that binds to the outermost layer of the skin cells. So that this substantive activity can be determined, the test is designed to extend over a 5-day testing period. Because of limitations of numbers of test subjects and the use of the opposite hand as a control, however, it is not possible to also run a vehicle and/or positive control in the same test. Certainly, other individual tests of these elements, including both vehicle and positive controls, can and should be designed. One option would be to run sequential tests on the same group. Obviously, the Commissioner would not discourage the development of such new tests. However, it is desirable to have a test for products, particularly hexachlorophene-containing products, that al-

lows judgment of the elements enumerated above for each product and comparisons between various antimicrobial chemicals to define the activity of surgical scrubs. Any agent which on initial or single use did no better than ordinary soap and water would not be acceptable as a surgical scrub.

The glove-juice test has been designed to eliminate as much variation as possible because tests with fewer subjects have not proven to be statistically valid. The procedures used in the test, the statistical evaluation procedures, and the criteria for definition as a surgical scrub were reviewed by several experts prior to use by FDA and adoption by the OTC Antimicrobial I Panel. The data submitted for the numerous hexachlorophene-containing products have clearly shown the value of this test in identifying products that are effectively formulated and products whose instructions do not allow sufficient exposures to the product to be effective. Collaborative studies are often time consuming and ultimately may merely show an already recognized interlaboratory variation.

Because of the unusual situation that hexachlorophene products were already being marketed when they were declared to be "new drugs," the number of tests required for an effective NDA is significantly fewer than for a new material being tested for safety and effectiveness. Certainly, further studies comparing a product to a vehicle control or a non-antimicrobial soap are desirable. In certain instances where the vehicle, e.g., alcohol, has obvious activity, vehicle controls have been requested.

5. One comment noted that the glove-juice test is based on a protocol proposed by the OTC Antimicrobial I Panel in the FEDERAL REGISTER of September 13, 1974, as part of the panel's proposed monograph for OTC topical antimicrobial products. It pointed out that, to date, neither the final monograph nor the comments on the proposed test has been published.

The Commissioner recognizes that the tentative final monograph has not been published, but, as indicated above, the glove-juice test has been required for surgical scrubs since 1973 and was adopted, with some changes, by the OTC Antimicrobial I Panel. The comments submitted on the proposed monograph concerning the glove-juice test dealt primarily with details of the test and its analysis and generally not with the criteria involved. As a result of these comments, some statistical changes in analysis are expected to appear in the tentative final monograph, but the test is expected to remain the same. Of course, all the comments received in response to the proposed monograph are on file with the Hearing Clerk, Food and Drug Administration, and are available for inspection.

6. One comment argued that for FDA to classify an already marketed drug as a new drug and then allow it to stay on the market before its NDA is approved is contrary to the provisions of section 505

of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). It also alleged that the preamble statement that the legality of transitional treatment of newly classified new drugs was recognized by the United States District Court for the District of Columbia in *Hoffmann-La Roche, Inc. v. Weinberger*, (Civil Action No. 75-0270 filed July 29, 1975), was entirely unfounded. Therefore, FDA should not finalize the proposed regulation, but should immediately prohibit the further marketing of new drugs containing hexachlorophene that are not the subject of an NDA.

The Commissioner rejects this comment because transitional treatment of newly classified new drugs was recognized and accepted by the court in "*Hoffmann-La Roche*." On October 31, 1975, June L. Green, U.S. District Judge, United States District Court for the District of Columbia, granted an FDA motion to amend and clarify the July 29, 1975 Order. The plaintiff (*Hoffmann-La Roche, Inc.*) concurred in this motion. The October 31 Order contained a typographical error, which was corrected by a revised Order reissued on November 3, 1975. The Court's Order of November 3, 1975 is as follows:

Further ordered, That the Court's Order of July 29, 1975, be amended to add the following separate final paragraph:

Ordered that nothing in the foregoing provisions of this Order shall prevent defendants, upon making and publishing in the FEDERAL REGISTER a determination that prescription new drugs in the following categories are medically necessary, from allowing such drugs to continue to be marketed pending completion of scientific studies required for an evaluation of their safety and effectiveness: (a) Drugs covered by approved new drug applications with respect to which new information causes defendants to initiate proceedings to withdraw approvals of applications pursuant to provisions of 21 U.S.C. 355 (e), and (b) drugs not previously declared as new drugs and not covered by effective new drug applications, which, upon the basis of new information, the defendants have classified as new drugs.

Dated: November 3, 1975.

JUNE L. GREEN,
District Judge.

This amendment to the Order of July 29, 1975, published in the FEDERAL REGISTER of March 2, 1976 (41 FR 9001), was cited in the preamble to the proposed regulation.

7. One comment objected, as an unduly restrictive regulatory approach, to the portion of the proposal that would prohibit the marketing of a new drug containing hexachlorophene upon the issuance of a notice of opportunity for hearing on a proposal to refuse to approve the NDA. It alleged that this would penalize a manufacturer who aggressively defended his product and would prevent the manufacturer from marketing a product earlier than another manufacturer who passively awaits the cut-off date. The comment also alleged that such a procedure appeared to be in conflict with § 314.200(a) (1) and (2) (21 CFR 314.200(a) (1) and (2)).

The condition that marketing would have to cease upon the publication of a

notice of opportunity for hearing was included in the proposal because a notice of opportunity for hearing constitutes the final decision of the Bureau of Drugs with respect to the application. After such a determination it would be contrary to the public interest to continue to permit the product to be shipped in interstate commerce pending final agency action on the application. A notice of opportunity for hearing would be published only if the manufacturer requests that the application be filed over protest. Such a request means that the manufacturer has completed studies and believes that sufficient data have been submitted for the application to be approved. Because the manufacturer contemplates no further studies, and the Bureau of Drugs has found the submitted studies unsatisfactory, it would be contrary to the provisions in "Hoffmann-LaRoche" (see paragraph 6) to allow continued marketing.

Although the comment alleged that the proposed procedure appears to be in conflict with § 314.200(a) (1) and (2), it offered no explanation or discussion of how the proposal conflicted. The Commissioner has reviewed these provisions and, finding nothing in them that conflicts with the proposed regulations, rejects this comment.

8. One comment recommended that FDA promulgate regulations establishing the circumstances under which transitional treatment is appropriate and a maximum 6-month period during which a new drug may be allowed to continue in a transitional status.

Although it is beyond the scope of the proposed regulation, the Commissioner has reviewed this comment. The Court's revised Order of November 3, 1975 in "Hoffmann-LaRoche," set out in paragraph 6 above, establishes that FDA can only employ the transitional treatment approach by publishing a determination in the FEDERAL REGISTER that the drug involved is medically necessary. This is the criterion to be followed by FDA, and there is no need to elaborate on it in a regulation.

The Commissioner also rejects the recommendation to establish 6 months as the maximum time to leave a drug in the transitional status. While it would be contrary to the spirit of "Hoffmann-LaRoche" to allow a transitional period to continue indefinitely, a time period of 6 months may be too short for some products. Thus, rather than set a time period applicable to all products, the Commissioner advises that in each FEDERAL REGISTER publication proposing transitional treatment of a newly classified new drug, he will propose a time limitation that is considered reasonable for that particular drug product.

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), § 250.250 is amended by revising the introductory text of paragraph (c) (4) to read as follows:

§ 250.250 Hexachlorophene, as a component of drug and cosmetic products.

(c) * * *

(4) Marketing of products for the indications listed in paragraph (c) (3) of this section may be continued without an approved new drug application (or required supplement thereto) either until a notice of opportunity for hearing is issued on a proposal by the Director of the Bureau of Drugs to refuse to approve such new drug application (or required supplement) or until January 31, 1978, whichever comes first, if all the following conditions were met after September 27, 1972:

Effective date: This amendment becomes effective on January 19, 1978.

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

Dated: December 13, 1977.

WILLIAM F. RANDOLPH,
Acting Associate
Commissioner for Compliance.

[FR Doc. 77-36173 Filed 12-19-77; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 510—NEW ANIMAL DRUGS

SUBPART G—SPONSORS OF APPROVED APPLICATIONS

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CER- TIFICATION

Primidone Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application (NADA) filed by Bolar Pharmaceutical Co., Inc., providing for use of a 250-milligram primidone tablet for treating dogs for certain forms of epilepsy, distemper, and hardpad disease.

EFFECTIVE DATE: December 20, 1977.

FOR FURTHER INFORMATION CON-
TACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Bolar Pharmaceutical Co., Inc., 130 Lincoln St., Copiague, N.Y. 11726, filed a NADA (107-397V) providing for use of a 250-milligram primidone tablet for the control of convulsions associated with idiopathic epilepsy, epileptiform convulsions, viral encephalitis, distemper, and hardpad disease that occurs as a clinically recognizable lesion in certain entities in dogs.

In accordance with the freedom of information regulations and § 514.11(e)

(2) (ii) of the animal drug regulations (21 CFR 514.11(e) (2) (ii)), a summary of safety data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFC-20), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Parts 510 and 520 are amended as follows:

1. In Part 510, § 510.600 is amended by adding a new sponsor alphabetically to paragraph (c) (1) and numerically to paragraph (c) (2) to read as follows:

§ 510.600 Names, addresses, and code numbers of sponsors of approved applications.

(c) * * *

(1) * * *

Firm name and address: Drug listing No.

Bolar Pharmaceutical Co., Inc., 130 Lincoln St., Copiague, N.Y. 11726.	000725
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(2) * * *

Drug listing No.: Firm name and address

000725.....	Bolar Pharmaceutical Co., Inc., 130 Lincoln St., Copiague, N.Y. 11726.
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2. In Part 520, § 520.1900 is amended by revising paragraph (b) to read as follows:

§ 520.1900 Primidone tablets.

(a) * * *

(b) Sponsor. See No. 000046 for use of 50- and 250-milligram tablets and No. 000725 for use of 250-milligram tablets in § 510.600(c) of this chapter.

Effective date: This regulation is effective December 20, 1977.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: December 9, 1977.

FRED J. KINGMA,
Acting Director, Bureau of
Veterinary Medicine.

[FR Doc. 77-36098 Filed 12-19-77; 8:45 am]

[4410-01]

Title 28—Judicial Administration

CHAPTER I—DEPARTMENT OF JUSTICE

PART 2—PAROLE, RELEASE, SUPERV- SION AND RECOMMITMENT OF PRIS- ONERS, YOUTH OFFENDERS, AND JU- VENILE DELINQUENTS

Paroling, Reccommitting and Supervising Federal Prisoners

AGENCY: The United States Parole Commission.

ACTION: Final rule.

SUMMARY: Certification of release-readiness by the Surgeon General (and appropriate drug treatment) is required prior to initial release on parole in the case of all prisoners serving Narcotic Addict Rehabilitation Act sentences. The regulation herein adopted eliminates the requirement for a re-certification by the Surgeon General in a case where the parole applicant is a returned parole violator whose parole was revoked for reasons other than involvement with drugs. The Commission has found that further drug treatment would not advance the statutory purpose where it would not be relevant to the behavior problem which caused the revocation.

EFFECTIVE DATE: February 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Michael A. Stover, Office of the General Counsel, U.S. Parole Commission, 320 First St., N.W., Washington, D.C. 20537, phone: 202-724-3092.

SUPPLEMENTARY INFORMATION: This will become effective for all re-parole consideration proceedings held on February 1, 1978, or thereafter. No re-certification will then be required for an applicant for re-parole under a NARA sentence when the findings upon which his revocation was based do not include any drug-related violations (use, possession, sale, etc.) while on parole.

Accordingly, pursuant to the provisions of 18 U.S.C. 4203(a)(1) and 4204(a)(6), 28 CFR Chapter I, Part 2, is amended as set forth below, effective February 1, 1978.

Dated: December 14, 1977.

Cecil C. McCall,
Chairman,
U.S. Parole Commission.

§ 2.3 Same; Narcotic Addict Rehabilitation Act.

A Federal prisoner committed under the Narcotic Addict Rehabilitation Act may not be released on parole prior to completion of a least 6 months in treatment, not including any period of time for study prior to final judgment of the court. Before parole is ordered by the Commission, the Surgeon General or his designated representative must certify that the prisoner has made sufficient progress to warrant his release and the Attorney General or his designated representative must also report to the Commission whether the prisoner should be released. Recertification by the Surgeon General prior to reparole consideration is not required unless the revocation of parole was based on drug-related violations. (18 U.S.C. 4254.)

[FR Doc. 77-36171 Filed 12-19-77; 8:45]

[4810-25]**Title 31—Money and Finance: Treasury****CHAPTER I—MONETARY OFFICES,
DEPARTMENT OF THE TREASURY****PART 103—FINANCIAL RECORDKEEPING
AND REPORTING OF CURRENCY AND
FOREIGN TRANSACTIONS****Modification of Reporting Requirement**

AGENCY: Department of the Treasury.

ACTION: Final rule.

SUMMARY: Each person having a financial interest in, or signature authority over a foreign financial account is required to report such relationship on his Federal income tax return and to provide such information concerning each such account as shall be specified in a special form to be filed by such persons. This amendment: (1) Alters the method of filing the report; and (2) exempts persons having a financial interest in 25 or more accounts from providing detailed information concerning each account unless so requested by the Secretary or his delegate. The regulation is being amended to that the required report will no longer be made in conjunction with filing tax return information, and to minimize the practical difficulties of reporting a large number of accounts by taxpayers having extensive international interests.

EFFECTIVE DATE: January 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert J. Stankey, Assistant to the Director (Financial Crimes and Frauds), Office of Law Enforcement, Department of the Treasury, Washington, D.C. 20220, 202-566-5630.

SUPPLEMENTARY INFORMATION: New Treasury Form 90-22.1, Report of Foreign Bank, Securities, and Other Financial Accounts will be filed with the Treasury Department on or before June 30th of each calendar year beginning with 1978 with respect to accounts maintained during the preceding calendar year.

Moreover, persons having a financial interest in 25 or more foreign accounts will be required to provide detailed information concerning each account only when so requested by the Secretary or his delegate. This modification in filing procedure is designed to minimize the practical difficulties of reporting a large number of accounts by taxpayers having extensive international interests. On August 15, 1977 Treasury permitted this procedures to be used for returns filed in 1977 and stated that the report form would be revised before it is time to file reports due in 1978. This amendment carries out that pledge.

The Department finds that since each of these changes is a modification or

liberalization of existing requirements, notice and public procedure with respect to these amendments is unnecessary under the provisions of 5 U.S.C. 553(b) and that good cause exists for making it effective less than 30 days after publication.

Accordingly, effective January 1, 1978, § 103.24 of Title 31 of the Code of Federal Regulations is amended to read as follows:

§ 103.24 Reports of foreign financial accounts.

Each person subject to the jurisdiction of the United States (except a foreign subsidiary of a U.S. person) having a financial interest in, or signature or other authority over, a bank, securities or other financial account in a foreign country shall report such relationship to the Secretary for each year in which such relationship exists, and shall provide such information as shall be specified in a reporting form prescribed by the Secretary to be filed by such persons. Persons having a financial interest in 25 or more foreign financial accounts need only note that fact on the form. Such persons will be required to provide detailed information concerning each account when so requested by the Secretary or his delegate.

Dated: December 8, 1977.

BETTE B. ANDERSON,
Under Secretary
of the Treasury.

[FR Doc. 77-36164 Filed 12-19-77; 8:45 am]

Title 32—National Defense**CHAPTER I—OFFICE OF THE
SECRETARY OF DEFENSE****SUBCHAPTER M—MISCELLANEOUS****PART 242a—PUBLIC MEETING PROCE-
DURES OF THE BOARD OF REGENTS,
UNIFORMED SERVICES UNIVERSITY OF
THE HEALTH SCIENCES****Change in Definition**

AGENCY: Uniformed Services University of the Health Sciences.

ACTION: Final rule.

SUMMARY: This rule changes the definition of meeting by changing the number of Regents whose deliberations constitute a meeting of the Board. The change is necessary to conform to the definition of quorum in the Board's General Procedures and Delegations.

EFFECTIVE DATE: January 19, 1978.

ADDRESS: Legal Counsel, Uniformed Services University of the Health Sciences, 4301 Jones Bridge Road, Bethesda, Md. 20014.

FOR FURTHER INFORMATION CONTACT:

Merel Glaubiger, Legal Counsel, 202-295-2113.