

that there is a genuine and substantial issue of fact that requires a hearing. If

and Drug Administration, Department of Health, Education, and Welfare

"§ 314.11(a)" should be changed to read "§ 314.11(b)".

analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice of opportunity for hearing shall be filed in quintuplicate. Such submissions, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1925, may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.82).

Dated: November 11, 1977.

J. RICHARD CROFT,
Director, Bureau of Drugs.

(FR Doc. 77-34370 Filed 12-1-77; 8:45 am)

[4110-03]

(Docket No. 77D-0351)

GUIDELINES FOR LEUKOCYTE TYPING SERUM

Notice of Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces the availability of guidelines for the production, testing, and lot release of Leukocyte Typing Sera for histocompatibility testing. The guidelines supersede those guidelines provided on December 14, 1973 in a memorandum from the Director, Bureau of Biologics, to manufacturers of Leukocyte Typing Sera.

EFFECTIVE DATE: December 2, 1977.

ADDRESS: Written comments (preferably in quadruplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) and requests for copies of the guidelines may be addressed to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Joe K. Holloway or Al Rothschild, Bureau of Biologics (HFB-620), Food

SUPPLEMENTARY INFORMATION: Notice is hereby given that guidelines for the production, testing, and lot release of Leukocyte Typing Sera for histocompatibility testing are on public display and are available upon request at the office of the Hearing Clerk, Food and Drug Administration.

Leukocyte Typing Sera consist of preparations of sera derived from blood obtained aseptically from humans or animals and contain an antibody or antibodies for identification of leukocyte antigens. The product is especially useful for identifying suitable donors for organ transplants and for use in platelet transfusions.

On December 14, 1973, the Bureau of Biologics issued guidelines to manufacturers from the production, testing, and lot release of Leukocyte Typing Sera. On November 11, 1976, the Bureau held an open Histocompatibility Testing Workshop, as announced in the FEDERAL REGISTER of October 19, 1976 (41 FR 46038), to reassess the 1973 guidelines. Approximately 60 attendees, consisting of scientists and industry and government representatives, attended the workshop. As a result of data and information presented at the workshop, updated guidelines have been prepared to replace the 1973 guidelines.

Copies of the guidelines are available upon request from the office of the Hearing Clerk.

Dated: November 21, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

(FR Doc. 77-34371 Filed 12-1-77; 8:45 am)

[1505-01]

Food and Drug Administration

(Docket No. 77N-0165)

NYLMERATE JELLY

Final Order on Objections and Requests for Hearing Regarding Withdrawal of Approval of New Drug Application

Correction

In FR Doc. 77-27968, appearing at page 49521 in the issue for Tuesday, September 27, 1977, make the following corrections:

(1) On page 49522, second column, under the heading "III Data Submitted * * *", in paragraph a, in the first line, after the phrase "Phenyl Mercury Nitrate—" insert the word "Its".

(2) On page 49523, first column, paragraph c, in the 13th line,

should be changed to read "(d)".

[4110-03]

(Docket No. 77N-0343; DESI 5554)

POVIDONE INJECTION AND GELATIN INJECTION

Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Applications

AGENCY: Food and Drug Administration (FDA).

ACTION: Notice.

SUMMARY: This notice proposes to withdraw approval of the new drug applications for povidone injection and gelatin injection of the basis that the drugs are not shown to be safe for use as plasma expanders in the emergency treatment of shock. The products are not being marketed.

DATES: Hearing requests due on or before January 3, 1978.

ADDRESSES: Communications forwarded in response to this notice should be identified with the reference number DESI 5554, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

Request for Hearing (identify with Docket number appearing in the heading of this notice): Hearing Clerk Food and Drug Administration (HFC-20), Rm. 4-65.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Implementation Project Manager (HFD-501) Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT:

Ronald L. Wilson, Bureau of Drug (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fisher Lane, Rockville, Md. 20857, 301-442-5650.

SUPPLEMENTARY INFORMATION

In a notice published in the Federal Register of August 19, 1971 (36 FR 16125), the Food and Drug Administration announced its conclusion that the products described below are effective as plasma volume expanders in the emergency treatment of shock.

NDA 9-564; Polyvinylpyrrolidone in Normal Saline containing 3.5 percent povidone in sodium chloride injection; McGaw Laboratories, 101 Grandview Ave., Glendale, CA 91201.

NDA 5-554; Knox Special Gelatine Solution Intravenous-6 percent containing 6 percent in sodium chloride injection; Knox Gelatine, Inc., 13 Knox Ave., Johnstown, N.Y. 12095.

The Director of the Bureau of Drugs now proposes to withdraw approval of the new drug applications for these drugs on the ground that new evidence, not contained in the applications or not available to the Food and Drug Administration until after the applications were approved, evaluated together with the evidence available when the applications were approved, shows that the drug products are not shown to be safe for use under the conditions for use upon the basis of which the applications were approved. Specifically, the Director refers to the following adverse effects which give an unfavorable benefit-to-risk ratio to these drugs and the fact that equally effective alternative drug products having less potential for risk are readily available.

POVIDONE INJECTION

A. Accumulates in the body and may cause storage disease with the formation of granulomas resembling sarcoid and metastatic tumors.

B. Interferes with blood coagulation, hemostasis, blood typing, and cross matching and may cause liver damage.

C. Interferes with the determination of protein and sugar in the urine.

GELATIN INJECTION

A. Lacks major requirements of a plasma expander, e.g., an osmotic pressure comparable to that of plasma, a viscosity suitable for infusion over a reasonable temperature range, a lack of antigenicity, and a lack of interference with blood typing and cross matching. (The drug has not been used clinically in this country for many years.)

B. Increases blood viscosity, which may cause blood sludging and thus induce intravascular coagulation.

C. Reduces platelet adhesiveness and prolongs bleeding time, which may cause hemorrhages.

REFERENCES

- Alexander, B., et al., "Coagulation, Hemostasis, and Plasma Expanders: A Quarter Century Enigma," *Federation Proceedings* 34(6):1429-1440, 1975.
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- Bojsen-Moller, M., et al., "The PVP Storage Disease," *Ugeskrift for Laeger* 138(17):1017-1020, 1976.
- Bubis, J.J., et al., "Storage of Polyvinylpyrrolidone Mimicking a Congenital Mucopolysaccharide Storage Disease in a Patient with Munchausen's Syndrome," *Israel Journal of Medical Science* 11(10):999-1004, 1975.
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- Evans, E. I. and H. S. Rafal, "Studies on Traumatic Shock: V. The Treatment of Clinical Shock with Gelatin," *Annals of Surgery* 121:473-491, 1945.
- Gaudiano, A., et al., *Bollettino della Società Italiana di biologia Sperimentale* 44:314, 1953.
- Gille, J. and H. Brandau, "Foreign Body Granulation in the Breast After Injection of a Polyvinylpyrrolidone Containing Preparation," (*Trans.*) *Geburtsh u Frauenheilk* 35(10):799-801, 1975.
- Goodman, L. S. and A. Gilman, *The Pharmacological Basis of Therapeutics*, 4th edition, 1970, p. 785-789.
- Huoper, W. C., "Bioassay on Polyvinylpyrrolidones with Limited Molecular Weight Range," *Journal of The National Cancer Institute* 26:229-237, 1961.
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- Koop, C. E. and L. Bullitt, "Gelatin as a Plasma Substitute," *American Journal of Medical Science* 209:28-33, 1945.
- Lorenz, W., et al., "Histamine release in Human Subjects by Modified Gelatin and Dextran: An Explanation for Anaphylactoid Reactions Observed Under Clinical Conditions?" *British Journal of Anaesthesia* 48:151-165, 1976.
- Lund, N., "Anaphylactic Reaction Induced by Infusion of Haemaccel," *British Journal of Anaesthesia (correspondence)* 45:929, 1973.
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- Ricketts, C. R., "Blood Substitutes," *British Journal of Anaesthesia* 45:959-962, 1973.
- Rudowski, W. and E. Koszewska, "Blood Substitutes," *Annals of the Royal College of Surgeons of England* 53:115-125, 1975.
- Schmidt, H. and H. Pfluger, "Nebenwirkungen bei Volumensubstitution mit Gelatinepräparaten," *Medizinische Welt* 22(26):1073-1077, 1971.
- Schneider, J. A., et al., "Comparison of the Effects of Various Blood Plasma Expanders on Platelet Adhesiveness," *Thrombosis et Diathesis Haemorrhagica* 24:185-190, 1970.
- Werner, F. M., "Destranen of Gelatines?" *Ned. Tijdschr. Geneesk.* 118(29):1121-1131, 1974.
- Wessel, W., et al., "Polyvinylpyrrolidone (PVP), Its Diagnostic, Therapeutic and Technical Application and Consequences Thereof," *Arzneimittel-Forschung* 21(10):1463-1462, 1971.
- Wisborg, K., "Anaphylactic reactions Induced by Infusion of Polygelin (Haemaccel)," *British Journal of Anaesthesia (correspondence)* 47:1116-1117, 1975.

Copies of these references are available for public examination in the office of the Hearing Clerk, and may be seen during working hours Monday through Friday.

Therefore, notice is given to the holder(s) of the new drug application(s) and to all other interested persons that the Director of the Bureau of Drugs proposes to withdraw

approval of the new drug applications for these drugs on the ground that new information before him with respect to the drug product(s), evaluated together with the evidence available to him at the time of approval of the applications, shows that such drugs are not shown to be safe for use under the conditions of use on the basis of which the applications were approved.

In addition to the holder(s) of the new drug applications specifically named above, this notice of opportunity for hearing applies to all persons who manufacture or distribute a drug product which is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for hearing to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Division of Drug Labeling Compliance (address given above).

In addition to the holder(s) of the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6) e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption from products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1952, or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Parts 310, 314), the applicant(s) and all other persons subject to this notice pursuant to 21 CFR 310.6 are hereby given an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and of all identical, related, or similar drug products.

If an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 elects to avail himself of the opportunity for a hearing, he should file

When notice of appearance and request for hearing is given, the sponsor of the drug is to notify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 314.200.

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of any such drug product. Any such drug product may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest on mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice shall be filed in quintuplicate. Submissions pursuant to this notice, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk between the hours of 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued 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 Director of the Bureau of Drugs (21 CFR 5.82).

Dated: November 18, 1977.

J. RICHARD CROUT,
Director, Bureau of Drugs.

(FR Doc. 77-34267 Filed 12-1-77; 8:45 am)

PROPOSED DRUGS AND DRUGS
SUSPENSIONS
Drugs for Human Use; Drug Efficacy Study
Implementation; Announcement

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces the conclusions of an efficacy review and sets forth the conditions for marketing propylidone oily and aqueous suspensions for the indication for which they are regarded as effective. The drug products are effective for use as diagnostic agents for radiographic visualization of the lungs.

DATE: Supplements to approved NDA's due on or before January 31, 1978.

ADDRESS: Communications forwarded in response to this notice should be identified with the reference number DESI 9309, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

Supplements (identify with NDA number): Division of Oncology and Radiopharmaceutical Drug Products (HFD-150), Room 17B-34.

Original abbreviated new drug applications and supplements thereto (identify as such): Division of Generic Drug Monographs (HFD-530), Bureau of Drugs.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD-501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT:

Herbert Gerstenzang, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice in the FEDERAL REGISTER of July 9, 1966 (31 FR 9426), each holder of a new drug application that became effective prior to October 10, 1962, was requested to submit to the Food and Drug Administration reports containing the best data available in support of the effectiveness of each such product for the claimed indications. That information was needed to facilitate a determination by the Food and Drug Administration, with the assistance of the National Academy of Sciences-National Research Council (NAS-NRC),

whether each claim in the labeling is

the sponsor of the following drug products, did not submit such information and therefore the drugs were not reviewed by NAS-NRC.

NDA 9-309; Dionosil Oily Suspension and Dionosil Aqueous Suspension, each containing propylidone; Picker Corp., 595 Miner Road, Cleveland, Ohio 44143.

Another notice published in the FEDERAL REGISTER of November 19, 1975 (40 FR 52609), invited Picker Corp., among other firms, to submit data on or before January 19, 1976. On March 17, 1976, Picker Corp. submitted data, which have been reviewed in conjunction with previously submitted information and determined to contain substantial evidence of effectiveness. This notice announces that conclusion and sets forth the conditions under which such drug products may be marketed.

Such drugs regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. An approved new drug application is a requirement for marketing such drug products.

In addition to the holder(s) of the new drug application(s) specifically named above, this notice applies to all persons who manufacture or distribute a drug product, not the subject of an approved new drug application, that is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Division of Drug Labeling Compliance (address given above).

A. *Effectiveness classification.* The Food and Drug Administration has reviewed all available evidence and concludes that the drug products are effective as described in the labeling conditions below.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* The drug product is in oily or aqueous suspension form suitable for intratracheal administration.

2. *Labeling conditions.* (a) The label bears the statement, "Caution: Feder-

Drugs. Other communications regarding this notice: Drug Efficacy Study Implementation project Manager (HFD-501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT:

Herbert Gerstenzang, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration announced its conclusions concerning the effectiveness of prochlorperazine drug products in the following notices:

DESI 11127, Docket No. FDC-D-499 (now Docket No. 77N-0258), published in the FEDERAL REGISTER of July 27, 1972 (37 FR 15038); and DESI 9149, Docket No. FDC-D-334 (also now Docket No. 77N-0258), published in the FEDERAL REGISTER of April 3, 1971 (36 FR 8447); as amended on November 2, 1971 (36 FR 20997).

The agency's conclusions were that the drug products described below are: (1) effective in the management of the manifestations of psychotic disorders and for the control of severe nausea and vomiting; (2) lacking substantial evidence of effectiveness for the control of behavior disorders in children, and for chronic alcoholism; and (3) possibly effective for its other labeled indication, which was for the control of excessive anxiety, tension, and agitation as seen in neuroses or associated with somatic conditions. Data submitted in response to the notices did support effectiveness of the drug products for the possibly effective indication. But in order to clarify that indication and more closely reflect the patient population that prochlorperazine was tested on in the three studies submitted, the indication is reworded to read as follows: "For the management of psychoneurotic patients displaying primarily symptoms of moderate to severe anxiety and tension."

The April 3, 1971, and July 27, 1972 notices also offered an opportunity for a hearing concerning the indications concluded at that time to lack substantial evidence of effectiveness. The notice that follows does not pertain to those indications. No person requested a hearing concerning them, and they are no longer allowable in labeling. Any such product labeled for those indications is subject to regulatory action. Other drugs included in the April 3, 1971, and July 27, 1972, notices but not named below are not affected by this notice.

1. NDA 10-371; Compazine Tablets;
2. NDA 10-742; Compazine Injection;
3. NDA 11-000; Compazine Spansules;
4. NDA 11-188; Compazine Syrup;
5. NDA 11-276; Compazine Concentrate;

and

6. NDA 11-127; Compazine Suppositories; all containing prochlorperazine; marketed by Smith Kline & French Laboratories, 1500 Spring Garden St., Philadelphia, Pa. 19101.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. An approved new drug application is a requirement for marketing such drug products.

In addition to the product(s) specifically named above, this notice applies to any drug product that is not the subject of an approved new drug application and is identical to a product named above. It may also be applicable, under 21 CFR 310.8, to a similar or related drug product that is not the subject of an approved new drug application. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufacturers or distributes. Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

A. Effectiveness classification. The Food and Drug Administration has reviewed all available evidence and concludes that the drug is effective for the indications in the labeling conditions below.

B. Conditions for approval and marketing. The Food and Drug Administration is prepared to approve new drug applications and supplements to previously approved new drug applications under conditions described herein.

1. **Form of drug.** The drug product is in tablet, syrup, concentrate, or controlled release capsule form suitable for oral administration; in sterile solution form suitable for parenteral administration; or in suppository form suitable for rectal administration.

2. **Labeling conditions.** (a) The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

(b) The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The indications are as follows:

For the management of the manifestations of psychotic disorders; for the control of severe nausea and vomiting; and for the management of psychoneurotic patients displaying primarily symptoms of moderate to severe anxiety and tension.

3. **Marketing status of approved products.** Marketing of such drug products that are now the subject of an approved or effective new drug application may be continued provided

that the holder of the application submits the following, if he has not previously done so, on or before June 1, 1978: (a) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (b) a supplement to provide full updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)).

4. **Marketing status of all other products.** (a) For all dosage forms of prochlorperazine, except for rectal suppository forms, approval of an abbreviated new drug application (21 CFR 314.1(f) containing full information with respect to items 6 (components), 7 (composition) and 8 (methods, facilities and controls) of new drug application form FD-356H (21 CFR 314.1(c)), may be obtained prior to marketing such product.

(b) For the rectal suppository form approval of a full new drug application must be obtained prior to marketing such product. The application shall contain the information specified in 21 CFR 314.1(c).

(c) Marketing prior to approval of new drug application will subject such products, and those persons who caused the products to be marketed, regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.70).

Dated: March 24, 1978.

J. RICHARD CROUT,
Director, Bureau of Drugs

(FR Doc. 78-3890 Filed 4-8-78; 8:45 am)

[4110-03]

(Docket No. 77N-0343; DESI 5554)

POVIDONE INJECTION AND GELATIN INJECTION

Withdrawal of Approval of New Drug Applications

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice withdraws approval of the new drug application for povidone injection and gelatin injection on the basis that the drugs are not shown to be safe for use as plasma expanders in the emergency treatment of shock. The products are not being marketed.

EFFECTIVE DATE: April 19, 1978.

ADDRESS: Requests for opinion on the applicability of this notice to

specific product should be identified with the reference number DESI 5554 and directed to: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Mary E. Catchings, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice of opportunity for hearing (DESI 5554, Docket No. 77N-0343) published in the *FEDERAL REGISTER* of December 2, 1977 (42 FR 81308), the Director of the Bureau of Drugs proposed to issue an order withdrawing approval of the following drug products on the ground that they are not shown to be safe for use under the conditions of use on the basis of which the applications were approved.

NDA 9-564: Polyvinylpyrrolidone in Normal Saline containing 3.5 percent povidone in sodium chloride injection; McGaw Laboratories, 1015 Grandview Ave., Glendale, Calif. 91201.

NDA 5-354: Knox Special Gelatine Solution Intravenous-8 percent containing 8 percent in sodium chloride injection; Knox Gelatine, Inc., 13 Knox Avenue, Johnstown, N.Y. 12095.

Any drug product intended for intravenous administration that is identical, related, or similar to the drug products named above, containing povidone or gelatine as an active ingredient, and is not the subject of an approved new drug application is covered by the new drug applications reviewed and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write the Division of Drug Labeling Compliance (address given above).

Neither the holders of the new drug applications nor any other person filed a written appearance of election as provided by the December 2, 1977, notice. The failure to file an appearance constitutes election by such persons not to avail themselves of the opportunity for a hearing.

The Director of the Bureau of Drugs, 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 him (21 CFR 5.82), finds that on the basis of new information before him with respect to the drug products, evaluated together with the evidence available to him when the applications were approved, such drugs are not shown to be safe for use under the conditions of use on the basis of which the applications were approved.

Therefore, pursuant to the foregoing finding, approval of new drug applications 9-564 and 5-354, and all amendments and supplements applying thereto, is withdrawn, effective April 19, 1978.

Shipment in interstate commerce of the above products or of any identical, related, or similar product that is not the subject of an approved new drug application will then be unlawful.

Dated: March 28, 1978.

J. RICHARD CROUT,
Director, Bureau of Drugs.

(FR Doc. 78-3894 Filed 4-8-78; 8:45 am)

[4110-83]

Health Resources Administration

GRANTS FOR RESIDENCY TRAINING IN GENERAL INTERNAL MEDICINE OR GENERAL PEDIATRICS

Application Announcement

The Bureau of Health Manpower, Health Resources Administration, announces that applications for fiscal year 1978 Grants for Residency Training in General Internal Medicine or General Pediatrics are now being accepted under the authority of section 784 of the Public Health Service Act, as amended by the Health Professions Educational Assistance Act of 1976 (Pub. L. 94-484).

Section 784 authorizes the award of grants to meet the costs of planning, developing and operating approved residency training programs in internal medicine or pediatrics which emphasize training for the practice of general internal medicine or general pediatrics and to assist participating residents who plan to practice general internal medicine or general pediatrics.

To receive support, programs must meet the requirements of the Interim-Final regulations, published in the *FEDERAL REGISTER* on November 18, 1977 (42 FR 58500). Eligible applicants are schools of medicine and osteopathy.

Requests for application materials and questions regarding grants policy should be directed to: Grants Management Officer, Bureau of Health Manpower, Health Resources Administration, Center Building, Room 4-22, 3700 East West Highway, Hyattsville, Maryland 20782, phone 301-436-6564.

To be considered for fiscal year 1978 funding, applications must be received by the Grants Management Officer, Bureau of Health Manpower, Health Resources Administration, at the above address no later than May 8, 1978.

Should additional programmatic information be requested, please contact: Professional Education and Development Branch, Division of Medicine, Bureau of Health Manpower,

Health Resources Administration, Center Building, Room 4-50, 3700 East West Highway, Hyattsville, Maryland 20782, phone 301-436-7350.

Dated: March 30, 1978.

HENRY A. FOLLY,
Administrator.

(FR Doc. 78-9061 Filed 4-8-78; 8:45 am)

[4110-24]

Institute of Museum Services

MUSEUM SERVICES PROGRAM

Notice of Closing Date for Receipt of Applications for Fiscal Year 1978

Notice is given that, under the authority contained in section 206 of the Museum Services Act, Pub. L. 94-462, title II (20 U.S.C. 965), applications from museums are being accepted under the Museum Services Program. The Museum Services Program provides Federal financial assistance to ease the financial burdens borne by museums as a result of their increased use by the public and to help them carry out their educational and conservation roles as well as other functions. Under this program grants are made to museums to maintain, increase, or improve museum services.

Closing date: June 2, 1978.

(a) *Application forms and information.* Application forms are being prepared but are not yet available. It is anticipated that application forms and program information packages will be ready for mailing to prospective applicants on or about April 18, 1978. The Institute plans to mail forms and program information packages to all museums which are members of the American Association of Museums and to all other institutions which request this material.

Applications must be prepared and submitted in accordance with the proposed regulation, instructions, and forms included in the program information packages.

(b) *Applications sent by mail.* An application sent by mail should be addressed to: U.S. Office of Education, Application Control Center, Attention: 13.923, Washington, D.C. 20202. (While the Institute is not part of the U.S. Office of Education, that Office is making available its facilities to receive applications invited under this notice.) Applications must be received by the Application Control Center on or before the closing date. An application sent by mail will be considered to be received on time by the Application Control Center if:

(1) The application was sent by registered or certified mail not later than May 29, 1978 as evidenced by the U.S. Postal Service postmark on the wrapper or envelope, or on the original receipt from the U.S. Postal Service; or