

[4110-03-M]

(Docket No. 78N-04201)

MEDICATED FEEDS**Availability of Task Force Report**

AGENCY: Food and Drug Administration

ACTION: Notice.

SUMMARY: This document announces the availability of a Food and Drug Administration (FDA) task force report entitled "Second Generation of Medicated Feeds."

ADDRESSES: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Copies of the report may be obtained from the Bureau of Veterinary Medicine, Industry Information Branch (HFV-226), 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William Bixler, Bureau of Veterinary Medicine (HFV-220), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4438.

SUPPLEMENTARY INFORMATION:

The purpose of the task force report is to examine FDA's current medicated feed program and make appropriate recommendations to the Commissioner of Food and Drugs for improvement. Implementation of these recommendations will lead to a more meaningful medicated feed program with emphasis on the human risks associated with such products. The report suggests that the medicated feed application process be modified in accord with the above emphasis to generally streamline it to lessen the paper work burden on industry and government alike.

The general concepts embodied in the report have been accepted by FDA's Director, Bureau of Veterinary Medicine and the Associated Commissioner for Regulatory Affairs. However, the Commissioner will not render the agency's final decision on the report's recommendations until a detailed manpower assessment and proposed implementation plan can be prepared. This additional information should be available to the Commissioner on or about April 1, 1979.

Written comments on the report are encouraged and may be addressed to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. A complete copy of the report including attachments may be seen in the Hearing Clerk's office between 9 a.m. and 4 p.m., Monday through

Friday. Copies of the report without the attachments may be obtained from the Bureau of Veterinary Medicine, Industry Information Branch (HFV-226), 5600 Fishers Lane, Rockville, MD 20857.

Dated: December 11, 1978.

JOSEPH P. HILL,
Associate Commissioner
for Regulatory Affairs.

(FR Doc. 78-34844 Filed 12-14-78; 3:45 am)

[4110-03-M]

(Docket No. 78N-0279; DESI 123741)

SPARTEINE SULFATE INTRAMUSCULAR INJECTION AND OXYTOCIN CITRATE BUCCAL TABLETS**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 sparteine sulfate intramuscular injection and oxytocin citrate buccal tablets. The ground for the action is that the drugs are not shown to be safe for use in the induction of labor and treatment of hypotonic uterine contractions.

DATE: Hearing requests due on or before January 15, 1979.

ADDRESSES: Communications forwarded in response to this notice should be identified with the Docket number 78N-0279, 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 (HFA-305), 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.

FOR FURTHER INFORMATION CONTACT:

Ronald L. Wilson, 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: Sparteine sulfate intramuscular injection and oxytocin citrate buccal tab-

lets have been used in the induction of labor and in cases of intrapartum hypotonic inertia. The drugs have pharmacological action of stimulating contraction of the uterus. As part of the Drug Efficacy Study Implementation (DESI), sparteine sulfate was evaluated by the National Academy of Sciences-National Research Council (NAS-NRC) as an effective drug for the induction of labor and treatment of hypotonic uterine contraction (Ref. 1). In their evaluation of the drug the NAS-NRC included a warning that the action of the drug is quite unpredictable and other methods are available that are more predictable and that can be better controlled.

After reviewing the NAS-NRC report on sparteine sulfate, the Food and Drug Administration (FDA) issued a notice (DESI 12374) in the FEDERAL REGISTER of June 17, 1971 (38 FR 11676), evaluating sparteine sulfate intramuscular injection as effective for the induction of labor and treatment of hypotonic uterine contractions. The notice required the following warning in the physician labeling:

The action of this preparation is quite unpredictable. It should not be given concomitantly with oxytocin. At least two hours should pass before a change is made from one drug to another. An occasional case rupture of the uterus has been reported with use of sparteine sulfate.

Oxytocin citrate buccal tablets were not included in the DESI review as a drug had been approved after the Drug Amendments of 1962. The physician labeling of this drug also contains the above warning statement.

In recent years the benefit/risk ratio for the use of sparteine sulfate intramuscular injection and oxytocin citrate buccal tablets for stimulation of the uterus has become of increasing concern to FDA. Medical literature has documented that stimulation of the uterus by the administration of these drugs during labor may lead to uterine tetany with marked impairment of the uteroplacental blood flow, uterine rupture, cervical and perineal lacerations, amniotic fluid embolism and trauma to the infant. Mothers and infants have been injured and some have died because of injudicious use of oxytocic drugs (Ref. 2).

At its meeting on July 18, 1975, FDA Obstetrics and Gynecology Advisory Committee considered the safety of sparteine sulfate, the danger of uterine contractions associated with the drug, and the unpredictability of its action. A subcommittee appointed to review all of the currently available information concerning sparteine sulfate intramuscular injection. Their report was submitted to the full Committee on October 3, 1975. The Committee concluded that because of the inability to control

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in obtaining ency task force o the Bureau of od and Drug Ad- treet-SW., Wash- A copy of the omplete adminis- oject is on display e Hearing Clerk. nistration, Rm 4- e, Rockville, Md. een in that office Monday through

1. 1979.

SEPH P. HILE,
Commissioner
Regulatory Affairs.
d 12-14-78; 3:45 am

drug's action and the documented problems of hypertonicity with the association of obstetrical complications, the relative safety of sparteine sulfate is in question and its approval for marketing should be discontinued.

The benefit/risk ratio of oxytocic drugs used in the induction of labor was again discussed in the November 17, 1977, and January 31, 1978 meetings of the Committee. The consensus of the Committee was that for induction or stimulation of labor only oxytocin injection, administered by the intravenous route, should be used as this mode of administration is more predictable and can be more adequately controlled. The potential dangers regarding the use of oxytocic drugs in the induction of labor were also discussed at the hearing on the use of injectable oxytocic drugs for elective induction of labor held on June 21, 1978. A notice announcing the hearing was published in the FEDERAL REGISTER of April 14, 1978 (43 FR 15779).

Medical literature concerning sparteine sulfate intramuscular injection and oxytocin citrate buccal tablets that has been published in recent years supports the findings of the FDA Obstetrics and Gynecology Advisory Committee that the action of the two drug products is unpredictable compared to the action of oxytocin intravenous injection. One article (Ref. 3) is an in vitro comparison of sparteine intramuscular injection and oxytocin intravenous injection on the human pregnant uterus muscle. The investigator found that the initial onset of action of sparteine is unpredictable compared with oxytocin. He also found that increasing the dose level of oxytocin over a very wide range of values resulted in no appreciable increase in muscle tonus, while with sparteine, as soon as dose levels are increased beyond minimal response levels, there is a highly significant increase in the baseline tonus. This suggests that if no effective uterine contractions are obtained with oxytocin the dose level may be safely raised. However, with sparteine, increasing dose levels presents increasing risk of tetanic contractions. Another article (Ref. 4) is by an investigator who conducted an objective evaluation of the in vitro and in vivo effects of sparteine sulfate on human uterine contractility. In vitro, he observed tetanic contractions with sparteine in concentrations of 300 micrograms per milliliter. In vivo, he noted that with sparteine, the increase in uterine activity is achieved principally by means of an increase in frequency of contractions, while with properly regulated oxytocin, the response is characterized by a more balanced increase in both frequency and amplitude. The effects on tonus were, again,

variable. In some cases the tonus remained unchanged while in others definite uterine hypertonus was observed. In one instance where such temporary tetanic activity was seen, the fetal heart rate was markedly depressed. Another interesting finding was the variation in response to equal doses of sparteine in the same individual. With serial injections of intramuscular sparteine, it was noted that the first dose usually produced the greatest increment in uterine activity. It is apparent that uterine activity cannot be regulated to the desired level with intramuscular sparteine sulfate as is possible with controlled oxytocin infusion. Examples of several adverse reactions following the use of sparteine have appeared in the literature. One report (Ref. 5) is a ruptured uterus and another report (Ref. 6) is a uterine tetany and fetal distress. Copies of references cited above and physician labeling for the drug products are on file with the Hearing Clerk.

REFERENCES

1. Drug Efficacy Study Report, National Academy of Sciences-National Research Council, on Tocosamine, sparteine sulfate.
2. A.M.A. Drug Evaluations, Third Edition, "Oxytocics," pp. 520-526.
3. Landesman, R., et al., "Sparteine and Oxytocin: In-Vitro Comparison on Pregnant-Uterus Muscle." *Obstetrics and Gynecology*, 23:2-3, 1964.
4. Goodno, J. A., et al., "In Vitro and In Vivo Effects of Sparteine Sulfate on Human Uterine Contractility—An Objective Evaluation." *Obstetrics and Gynecology*, 86:288-290, 1963.
5. Boysen, H., "Sparteine Sulfate and Rupture of the Uterus: Report of a Case." *Obstetrics and Gynecology*, 21:403-404, 1963.
6. Bedrosian, L. and J. J. Gamble, "Uterine Tetany and Fetal Distress Coincidental with Administration of Sparteine Sulfate: Report of a Case." *Obstetrics and Gynecology*, 21:400-402, 1963.
7. Greenhill, J. P. and E. A. Friedman, "Biological Principles and Modern Practice of Obstetrics." W. B. Saunders Co., Philadelphia, p. 309, 1974.
8. Page, E. W., C. I. Villie, and D. B. Villie, "Human Reproduction," 2d Ed., W. B. Saunders Co., Philadelphia, p. 306, 1976.
9. Pritchard, J. A. and P. C. MacDonald, "Williams Obstetrics," 15th Ed., Appleton-Century-Crofts, New York, p. 662, 1976.
10. Transcript of the Obstetrics and Gynecology Advisory Committee Meeting, July 18, 1975.
11. Transcript of the Obstetrics and Gynecology Advisory Committee Meeting, October 2, 1975.
12. Transcript of the Obstetrics Gynecology Advisory Comm Meeting, November 17, 1977.
13. Transcript of the Obstetrics Gynecology Advisory Comm Meeting, January 31, 1978.
14. Transcript of the Proceedin the Hearing on Elective Inductio Labor—Injectable Oxytocic I June 21, 1978.
15. Tocosamine Sterile Solutio Intramuscular Use Only, lab 1971.
16. Spartocin Sterile Solution f Intramuscular Use Only, Labeling, 1971.
17. Pitocin Citrate Buccal Tabl Buccal Administration Only, lab 1975.

The Director of the Bureau of now proposes to withdraw appro the new drug applications for teine sulfate intramuscular inj and oxytocin citrate buccal tabl and the ground that new evidenc contained in the applications c available to the Food and Drug ministration until after the a tions were approved, evaluated t er with the evidence available the applications were approved, that the drug products are not to be safe for use under the con for use upon the basis of which plications were approved. Spec the Director refers to the seriou of uterine tetany and fetal distr sociated with the use of these which give an unfavorable ben risk ratio to such drugs for th beled indications, and the fact t ytocin intravenous injection, less potential for risk, is readily ble.

This notice applies not only t teine sulfate intramuscular inj which was subject to the DESI and oxytocin citrate buccal i which was approved after the Amendments of 1962, but to a products that are the subject of drug application approved before or after the Drug Amend of 1962 and also to any identical ed, or similar drug product (2 310.6) whether or not it is the of an approved new drug applic • NDA 12-374; Tocosamine Ste lution containing sparteine Trent Pharmaceuticals, Inc., chester Plaza, Elmsford, NY 105 • NDA 13-211; Spartocin I containing sparteine sulfate; Laboratories, Division American Products Corp., 885 Third Av York, NY 10017. • NDA 13-508; Pitocin Citrate Tablets containing oxytocin Parke, Davis & Co., Joseph C Ave. at the River, Detroit, MI 4

It is the responsibility of eve manufacturer or distributor to this notice to determine whe covers any drug product th

NOTICES

person manufactures 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).

Therefore, notice is given to the holders of the new drug applications and to all other interested persons that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug applications and all amendments and supplements thereto on the ground that new evidence of clinical experience, not contained in such applications or not available until after such applications were approved, evaluated together with the evidence available when the applications were approved, shows that such drugs are not shown to be safe for use in the induction of labor and treatment of hypotonic uterine contractions.

In addition to the specific ground for 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, e.g., any contention that a 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 for 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 1962, 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 applicants and all other persons who manufacture or distribute a drug product that is identical, related, or similar to a drug product named above (21 CFR 310.6) are hereby given an opportunity for a hearing to show why approval of the new drug applications should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to its legal status.

An applicant or any other person subject to this notice who decides to seek a hearing, shall file (1) on or before January 15, 1979, a written notice of appearance and request for hearing, and (2) on or before February 13, 1979, the data, information, and analyses relied upon to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this proposal to withdraw approval. 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 the person not to make use of the opportunity for a hearing concerning the action proposed with respect to the product and constitutes 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 upon 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 that 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 of Food and Drugs 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. 1905, 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 (sec. 505, 52 Stat. 1052-1053 as amended (21 U.S.C. 352, 355)), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 5.82).

Dated: November 30, 1978.

J. RICHARD CROTT,
Director, Bureau of Drugs.

(FR Doc. 78-34593 Filed 12-14-78; 3:45 am)

[4110-92-M]

FEDERAL COUNCIL ON THE AGING;
TERM CARE COMMITTEE

Meeting

The Federal Council on the Aging was established by the 1973 amendments to the Older Americans Act of 1965 (Pub. L. 93-29, 42 U.S.C. 3015) for the purpose of advising the President, the Secretary of Health, Education and Welfare, the Commissioner of Aging, and the Congress on matters relating to the special needs of older Americans.

Notice is hereby given pursuant to the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C. app. 1, sec. 101, 1976) that the Long Term Care Committee of the Council will hold a meeting on Friday, January 12, 1979 from 9:30 a.m. to 12:30 p.m., Rooms 70705A, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, D.C. 20201.

The agenda will consist of a discussion of issues in long term care with representatives of Federal Departments.

Further information on the Council may be obtained from the FCA Secretariat, Federal Council on the Aging, Washington, D.C. 20201, telephone 202-245-0441. FCA meetings are open for public observation.

Dated: December 11, 1978.

NELSON H. CRUIKSHANK,
Chairman, Federal Council
on the Aging.

(FR Doc. 78-34901 Filed 12-14-78; 3:45 am)

[4110-92-M]

MODEL ADOPTION LEGISLATION AND
PROCEDURES ADVISORY PANEL

Meeting

The Model Adoption Legislation and Procedures Advisory Panel was established by the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978 (Public Law 95-266, Title II, Section 202) to advise and assist the Secretary of HEW in the review of current conditions, practices, and laws relating to adoption, with special reference to their effect on facilitating or impeding the location of suitable adoptive homes for children who would benefit by adoption and the completion of suitable adoptions for such children. The Panel will propose to the Secretary model adoption legislation and procedures not later than twelve months after its appointment.

Notice is hereby given pursuant to the Federal Advisory Committee Act (Public Law 92-463, 5 U.S.C. app. 1, sec. 10, 1976) that the Panel will hold

and receivers to obtain transportation at less than such rates or charges by unjust and unfair devices or means, all in violation of sections 16 and 18(b)(3) of the Shipping Act, 1916.

Hearing in this matter, if any is held, shall commence on or before January 31, 1980. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon a proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record.

Francis C. Hurney,
Secretary.

[FR Doc. 79-24229 Filed 8-6-79; 8:45 am]
BILLING CODE 3730-01-M

FEDERAL TRADE COMMISSION

Transmittal Rules; Early Termination of Waiting Period of the Premerger Notification Rules

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the 30-day waiting period of the premerger notification rules.

SUMMARY: MAPCO, Inc. is granted early termination of the 30-day waiting period provided by law and the premerger notification rules with respect to its proposed acquisition of Filon Exploration Corporation. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to requests for early termination submitted by both parties to the transaction. neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: July 27, 1979

FOR FURTHER INFORMATION CONTACT: Malcolm R. Pfunder, Assistant Director for Evaluation, Bureau of Competition, Room 394, Federal Trade Commission, Washington, D.C. 20580. (202-523-3404).

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. § 18a, as added by sections 201 and 202 of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b) (2) of the Act and

§ 803.11 of the rules implementing the Act permit the agencies, in individual cases, to terminate this waiting period prior to its expiration and require that notice of this action be published in the Federal Register.

By direction of the Commission.
Carol M. Thomas
Secretary.

[FR Doc. 79-24231 Filed 8-6-79; 8:45 am]
BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Center for Disease Control

Preliminary Planning for American Group Providers of Occupational Safety and Health Services and Self-Contained Breathing Apparatus (SCBA) Course Curriculum; Open Meetings

Preliminary Planning for American Group Providers of Occupational Safety and Health Services

DATE: August 17, 1979.

TIME: 9:30 a.m. to 4:30 p.m.

PLACE: Room 117, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

PURPOSE: To discuss preliminary plans for an education meeting, which will be held in the greater Washington, D.C., area concerning the provision of occupational safety and health services.

ADDITIONAL INFORMATION MAY BE OBTAINED FROM: Loren L. Hatch, D.O., Ph.D., Division of Technical Services, National Institute for Occupational Safety and Health, Center for Disease Control, 4676 Columbia Parkway, Cincinnati, Ohio 45226. Telephone: 513/684-8311.

Self-Contained Breathing Apparatus (SCBA) Course Curriculum

DATE: August 23, 1979.

TIME: 9 a.m. to 4 p.m.

PLACE: Auditorium Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

PURPOSE: To discuss the development of a training course for trainers in the proper use and maintenance of SCBA.

ADDITIONAL INFORMATION MAY BE OBTAINED FROM: N. J. Berbenich, Jr., Ph.D., Division of Training and Manpower Development, National Institute for Occupational Safety and Health, Center for Disease Control, 4676 Columbia Parkway, Cincinnati, Ohio 45226. Telephone: 513/684-8321.

Dated: August 2, 1979.

William H. Foege, M.D.,

Director, Center for Disease Control.

[FR Doc. 79-24444 Filed 8-7-79; 8:45 am]

BILLING CODE 4110-87-M

Food and Drug Administration

Immunology Devices Section of the Immunology and Microbiology Devices Panel; Meeting Cancellation

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The meeting of the Immunology Devices Section of the Immunology and Microbiology Devices Panel, which was scheduled for August 16 and 17, 1979, and announced by notice in the Federal Register of July 17, 1979 (41 FR 41546), has been cancelled.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 3757 Georgia Ave., Silver Spring, Md., 301-427-7234.

Dated: July 31, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-29114 Filed 8-3-79; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 78N-0279; DESI 12374]

Sparteine Sulfate Intramuscular Injection and Oxytocin Citrate Buccal Tablets; Withdrawal of Approval of New Drug Applications

AGENCY: Food and Drug Administration.
ACTION: Withdrawal of approval.

SUMMARY: This notice withdraws approval of the new drug applications for Tocosamine Sterile Solution and Spartocin Injection containing sparteine sulfate. The basis for the withdrawal is that the drug products have not been shown to be safe for use in inducing labor and treatment of hypotonic uterine contractions.

EFFECTIVE DATE: August 17, 1979.

ADDRESS: Requests for opinion of the applicability of this notice to a specific product should be identified with the number DESI 12374 and directed to the Division of Drug Labeling Compliance (HFD-310) Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Suzanne O'Shea, 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 the notice for opportunity for hearing, published in the Federal Register of December 15, 1978 (43 FR 58634), the Director of the Bureau of Drugs proposed to issue an order withdrawing approval of the following drug products because they are not shown to be safe when used for their labeled indications and because oxytocin intravenous injection, having less potential for risk, is readily available.

NDA 12-374: Tocosome Sterile
Solution containing sparteine sulfate;
Trent Pharmaceuticals, Inc., 8
Winchester Plaza, Elmsford, NY 10523.

NDA 13-211: Spartocin Injection
containing sparteine sulfate; Ayerst
Laboratories, Division American Home
Products Corp., 685 Third Ave., New
York, NY 10017.

NDA 13-308: Pitocin Citrate Buccal
Tablets containing oxytocin citrate;
Parke-Davis, Division of Warner-
Lambert Co., Morris Plains, NJ 07950.

In response to the notice, Parke-Davis requested a hearing for its product. That request is under review, and will be the subject of a future notice. This notice, therefore, does not apply to NDA 13-508, and marketing of the Parke-Davis product may continue pending a ruling on the hearing request.

No person other than Parke-Davis filed a written notice of appearance and request for hearing as provided by the December 15, 1978 notice. The failure to file a notice of appearance and request for a hearing constitutes an election by such persons not to avail themselves of an opportunity for a hearing.

Any drug product that is identical, related, or similar to the drug products named above and that 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 to the Division of Drug Labeling Compliance at the address given above.

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 evidence of clinical experience, not contained in the applications or not available until after the applications were approved, evaluated together with the evidence available to him when the applications were approved, the drugs

are not shown to be safe for use in the induction of labor and treatment of hypotonic uterine contractions.

Therefore, pursuant to the foregoing finding, approval of new drug applications 12-374 and 13-211 and all amendments and supplements applying thereto is withdrawn effective August 17, 1979.

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. Parke-Davis' Pitocin Citrate Buccal Tablets, which is the subject of a pending hearing request, may continue to be marketed.

Dated: July 26, 1979.

Jerome A. Halperin,

Acting Director, Bureau of Drugs.

(FR Doc. 79-24243 Filed 8-7-79; 8:45 am)

BILLING CODE 4110-03-M

[Docket No. 79N-0207]

Plascon, Inc.; revocation of U.S. License No. 572

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) revokes the establishment and product license (U.S. License No. 572) issued to Plascon, Inc., for the manufacture of Source Plasma (Human) because of significant deviations from the biologics regulations.

EFFECTIVE DATE: May 24, 1979.

FOR FURTHER INFORMATION CONTACT: Richard E. Fisher, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration has revoked the establishment and product licenses (U.S. License No. 572) issued to Plascon, Inc., T/A Indy Plasma Center, 3764 N. Illinois St., Indianapolis, IN 46208, for the manufacture of Source Plasma (Human).

An inspection of this location on February 21, 22, 23, and 26, 1979, by investigators of the Food and Drug Administration (FDA) revealed numerous deviations from the requirements of Parts 600, 606, and 640 including, but not limited to, the collection of more than the maximum permissible amount of whole blood from donors at one time (21 CFR 640.65(b)(6)). This significant deviation was one of many items cited in a previous FDA

inspection of this location in November 1978, which resulted in the suspension of the firm's operations under license on November 8, 1978. The firm's operations had been previously suspended from May 8, 1978 through June 5, 1978 for failure to report a change in responsible personnel (21 CFR 601.12(a)).

As a result of the February 1979 inspection, FDA advised the responsible head by letter dated March 16, 1979, that after being given a reasonable time to demonstrate compliance following the second license suspension, he had failed to exercise necessary control and supervision in all matters relating to compliance with applicable rules and regulations; the letter also stated FDA's intention to revoke U.S. License No. 572 and issue a notice of opportunity for hearing under 21 CFR 601.5(b).

Following receipt of the March 16, 1978 letter and before initiation of further regulatory action, the firm requested that its establishment and product license be revoked and waived the opportunity for a hearing under § 601.5(a) (21 CFR 601.5(a)). The agency has granted the request. Accordingly, under § 12.38 (21 CFR 12.38), and section 351 of the Public Health Service Act (42 U.S.C. 262), and the authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director, Bureau of Biologics (21 CFR 5.68), U.S. License No. 572 issued to Plascon, Inc., and the Product License for the manufacture of Source Plasma (Human) were revoked by letter dated May 24, 1979. This notice of revocation is published under § 601.5 (21 CFR 601.8).

Dated: August 1, 1979.

William F. Randolph,

Acting Associate Commissioner for
Regulatory Affairs.

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HEALTH, EDUCATION, AND WELFARE

Office of Education

National Advisory Council on the Education of Disadvantaged Children; Meetings

Notice is hereby given pursuant to Pub. L. 92-463, that the National Advisory Council on the Education of Disadvantaged Children will hold meetings in Los Angeles, California from Thursday, August 23 through Friday, August 25, 1979. On August 23, the Council's Committee on Regulations will meet from 1 p.m. to 6 p.m. The Council will host its regular meeting on August 24 from 9 a.m. to 5 p.m., and on August