Fellows – Testagar
DIVISION OF FELLOWS MEDICAL MFG. CO., INC.
PHARMACEUTICALS SINCE 1866

PHONE 962-6126
AREA CODE 313

1334 W. LAFAYETTE BLVD.
DETROIT 26, MICHIGAN

2/11/65

February 9, 1965

our - uns. - nuestra ref. THOROTRAST
your letter - Ihr schr. - su carta Tel. 2-8-65
your - Ihre - su ref.

Mr. Walter A. Radeloff
U. S. Atomic Energy Commission
Division of Compliance, Region 3
Professional Building
410 Oakbrook
Oak Brook, Illinois - 60523

Dear Mr. Radeloff:

As per our telephone conversation on February 8, 1965, regarding THOROTRAST, we are sending you today under separate cover the following:

1. Copies of all invoices, domestic and export, for THOROTRAST, for the time period of January 1, 1964 to June 30, 1964.

2. Labeling of THOROTRAST in use before the announcement of the Food and Drug Administration, published in the Federal Register on June 6, 1964, regarding drugs containing Thorium Dioxide.

3. Present Labeling of THOROTRAST for Export, which is the same labeling as under 2. above, but stamped "For Export Only."

4. Present Labeling of THOROTRAST for Domestic Use (for animal use only).

Hoping that the above will give you all the information you wish, we remain,

Sincerely yours,

FELLOWS-TESTAGAR

Richard H. Carrigan

Richard H. Carrigan
Vice President
Scientific Administration

RHC:z

CC: S.J.H.

DSS
2/12/65

Note:

Dr. Western talked with C. F. Bruening, FDA today concerning the "Thorotrast" matter.

Mr. Bruening advised Dr. Western that they are coming out with a policy statement which will be published in the Federal Register on Tuesday, February 16, 1965.

This statement will indicate that "Thorotrast" may be used for the following purposes:

1) Primary or secondary live tumors.

2) Cystic malignant tumors of the brain for monitoring purposes.

Mr. Bruening is Dr. Myers Assistant.

Margaret

[illegible] on the southwest side of State Secondary Highway 28 and 0.6 mile northwest of the junction of said highway and U.S. Highway 15.

The Lois P. Hamer farm located on both sides of a dirt road 0.1 mile north of the junction of said dirt road and U.S. Highway 15, said junction being 0.1 mile northwest of the intersection of U.S. Highway 15 and State Secondary Highway 22 at Tatum.

The James Joseph farm located on the southeast side of State Secondary Highway 165 and 1.2 miles southwest of its intersection with State Secondary Highway 257.

The Lula McEachern farm located on the north side of U.S. Highway 15 at the intersection of said highway and the South Carolina-North Carolina State line.

The Cleveland McKay farm located on the north side of State Secondary Highway 54 and the west side of State Secondary Highway 30 at the intersection of said highways.

The Mable N. McQueen farm located on the northwest side of State Secondary Highway 48 and 0.2 mile southwest of the junction of said highway and State Secondary Highway 22.

The Ina Odom farm located on the northwest side of a dirt road and 0.4 mile northeast of its junction with State Secondary Highway 30, said junction being 0.3 mile northeast of the intersection of said highway and State Secondary Highway 54.

The D. M. Parker farm located on the northeast side of State Secondary Highway 28 and 0.2 mile northwest of its junction with U.S. Highway 15.

The Archie Pearson farm located on the east side of a dirt road 0.5 mile southwest of the junction of said dirt road and State Primary Highway 79, said junction being 0.3 mile south of the intersection of said highway and State Secondary Highway 71.

The D. C. Rainwater farm located on the west side of State Primary Highway 79 at the junction of said highway and State Secondary Highway 345.

The Tony Rosser farm located on the east side of a dirt road and 0.6 mile northeast of the junction of said dirt road and State Secondary Highway 30, said junction being 0.3 mile north of the junction of said highway and State Secondary Highway 54.

The James Tyson Smith farm located on the northwest side of State Secondary Highway 165 and 1.2 miles southwest of its intersection with State Secondary Highway 257.

The Pauline Steel farm located on the north side of State Secondary Highway 63 and the east side of Crooked Creek at the intersection of said highway and creek.

The Marvin Strong farm located on the south side of the South Carolina-North Carolina State line and 1.3 miles east of its junction with State Primary Highway 177.

Williamsburg County. The Ernest V. Carter farm located on the north side of a dirt road and 1.6 miles west of its junction with State Secondary Highway 51, said junction being 0.8 mile south of the junction of said highway and State Primary Highway 261.

The S. Wayne Gamble farm located on both sides of State Primary Highway 375 and 2 miles southeast of its intersection with U.S. Highway 52.

(Sec. 9, 37 Stat. 318, sec. 106, 71 Stat. 33; 7 U.S.C. 162, 150ee; 29 F.R. 16210; 7 CFR 301.80–2. Interprets or applies sec. 8, 37 Stat. 318, as amended; 7 U.S.C. 161)

These revised administrative instructions shall become effective February 16, 1965, when they shall supersede P.P.C. 627, seventh revision, effective March 24, 1964 (7 CFR 301.80–2a).

The purpose of this revision is to include within the regulated areas additional farms and areas in the following partially regulated counties: North Carolina—Counties of Brunswick, Columbus, Cumberland, Duplin, Hoke, Johnston, Jones, Lenoir, Onslow, Pender, Richmond, Sampson, Scotland, and Wayne; South Carolina—Chesterfield, Darlington, Florence, Horry, Marion, and Marlboro.

The restrictions imposed are necessary in order to prevent the interstate spread of the witchweed. This revision should be made effective promptly in order to accomplish its purpose in the public interest. Accordingly, under section 4 of the Administrative Procedure Act (5 U.S.C. 1003), it is found upon good cause that notice and other public procedure with respect to the foregoing revision are impracticable and contrary to the public interest, and good cause is found for making the effective date thereof less than 30 days after publication in the FEDERAL REGISTER.

Done at Hyattsville, Md., this 11th day of February 1965.

[SEAL] E. D. BURGESS,
Director,
Plant Pest Control Division.

[F.R. Doc. 65-1637; Filed, Feb. 15, 1965; 8:49 a.m.]

Title 14—AERONAUTICS AND SPACE

Chapter I—Federal Aviation Agency

[Docket No. 6362; Amdt. 39-32]

PART 39—AIRWORTHINESS DIRECTIVES

Beech Model 35 Series Aircraft

A proposal to amend Part 507 of the Regulations of the Administrator to include an airworthiness directive to revise AD's 57-18-1, 62-8-3, and 63-25-1, to extend the applicability to cover model designations which did not exist at the time of original publication on Beech Model 35 Series aircraft was published in 29 F.R. 16429. Since the publication of that proposal, Part 507 has been recodified into Part 39, effective November 20, 1964, therefore this amendment is being made to Part 39.

Interested persons have been afforded an opportunity to participate in the making of the amendment. No objections were received.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (25 F.R. 6489), § 39.13 of Part 39 (14 CFR Part 39), is amended as follows:

1. Amendment 3, 23 F.R. 438, AD 57-18-1, is amended by changing the applicability and compliance statements to read:

Applies to Model 35 Series aircraft and Model Super V conversions of standard Beech Models 35, A35 or B35.

A. Applies to Model 35 aircraft Serial Numbers D-1 through D-1500 and Model Super V aircraft Serial Numbers SV-XXX-D-1 through SV-XXX-D-1500.

Compliance required within 100 hours' time in service after the effective date of this amendment unless already accomplished, and thereafter within 100 hours' time in service from the last inspection.

B. Applies to Models 35 and Super V aircraft.

Compliance required within 100 hours' time in service after the effective date of this amendment unless already accomplished.

2. Amendment 421, 27 F.R. 3652, AD 62-8-3, is amended by changing the applicability and compliance statements and by changing paragraph (c) to read:

Applies to Models 35, 50, 65, and 95 Series aircraft and Model Super V conversions of the standard Beech Models 35, A35, or B35 with white plastic rams horn control wheels installed as original equipment or by kit installation in the field.

Compliance required within 100 hours' time in service after the effective date of this amendment unless already accomplished.

(c) Inspections may be discontinued when metal replacement control wheel, P/N 35-380057 for Models 35 and 95 Series and Model Super V, and P/N 50-350025 for Models 50 and 65 Series, or an FAA-approved equivalent is installed.

3. Amendment 652, 28 F.R. 12926, AD 63-25-1, as revised by Amendment 719, 29 F.R. 5542, is further amended by changing the applicability and compliance statements to read:

Applies to Model 35 aircraft Serial Numbers D-1 through D-1500, Model 35R aircraft Serial Numbers D-XXR1 and up (35R aircraft are remanufactured Model 35 aircraft and retain the original serial number in addition to the appropriate 35R serial number), and Model Super V conversions of the standard Beech Models 35, A35, or B35 Serial Numbers SV-XXX-D-1 through SV-XXX-D-1500.

Compliance required within 25 hours' time in service after the effective date of this amendment unless already accomplished within the last 75 hours' time in service and thereafter within 100 hours' time in service from the last inspection.

This amendment shall become effective March 18, 1965.

(Secs. 313(a), 601, 603; 72 Stat. 752, 775, 776; 49 U.S.C. 1354(a), 1421, 1423)

Issued in Washington, D.C., on February 9, 1965.

HARRY A. TURNPAUGH,
Acting Director,
Flight Standards Service.

[F.R. Doc. 65-1595; Filed, Feb. 15, 1965; 8:45 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER A—GENERAL

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

Thorium Dioxide for Drug Use

On the basis of recommendations of the Committee on Drugs and New Devices of the American College of Radiology, given general approval by the Board of the American College of Radiology, the Commissioner of Food and Drugs has determined that the regulation (21 CFR 3.36) dealing with the labeling of drugs containing thorium

2/16/65

dioxide should be amended as hereinafter set forth. Therefore, under the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 502(f), 701(a), 52 Stat. 1050, as amended; 1055; 21 U.S.C. 352(f), 371 (a)), and delegated to the Commissioner (21 CFR 2.90), § 3.36 is revised to read as follows:

§ 3.36 Thorium dioxide for drug use.

(a) Thorium dioxide is a source of naturally occurring radioactivity that has been used over a period of years as a radiopaque medium. When thorium dioxide is injected, it is permanently stored in the body. Because of its radioactivity, this storage causes scarring and carcinogenesis in the area of storage. There are reports in the medical literature of malignancy and deaths resulting from the injection of thorium dioxide. Therefore, the use in man of drugs containing thorium dioxide is justified only when this drug has a unique clinical usefulness and there is substantial evidence of limited life expectancy by reason of disease or advanced age. The administration of the drug to food-producing animals cannot be justified since it may result in residues of the drug in food.

(b) Drugs containing thorium dioxide are unsafe and are regarded as misbranded within the meaning of section 502 (f) (1), (2), and (j) of the Federal Food, Drug, and Cosmetic Act when labeled or advertised for administration to man except when they have a unique clinical usefulness and there is substantial evidence of limited life expectancy by reason of disease or advanced age.

(c) Drug preparations containing thorium dioxide may be approved for marketing on the basis of new-drug applications containing labeling bearing, in addition to other requirements, information to the following effect, which differs substantially from the labeling that has been employed in the past in the marketing of such drugs:

(1) *Warning.* For use only when this drug has a unique clinical usefulness and there is substantial evidence of limited life expectancy by reason of disease or advanced age. Not for administration to food-producing animals.

(2) *Precautions.* Special precautions should be taken to prevent soft tissue extravasation of the injected material. Precautions should be taken to prevent injection of thorium dioxide into the subarachnoid space.

(3) *Indications for use.* For demonstration of primary or secondary tumors in the liver; for the delineation of the wall of a cystic malignant brain tumor when such delineation is deemed advantageous for purposes of progressive monitoring in the course of therapy.

(4) *Dosage.* Minimum amount necessary for adequate visualization should be utilized.

(d) A new-drug application will be regarded as approvable if it contains appropriate labeling conforming to the provisions of paragraph (c) of this section and satisfactory information of the kinds required by items 2, 3, 4, 6, 7, and 9 of the new-drug application form contained in § 130.4(c) of this chapter.

(Secs. 502(f), 701(a), 52 Stat. 1050 as amended; 1055; 21 U.S.C. 352(f), 371(a))

Dated: February 1, 1965.

JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 65-1639; Filed, Feb. 15, 1965; 8:49 a.m.]

PART 120—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Inorganic Bromides; Tolerance for Residues

Comments on the proposal of the Commissioner of Food and Drugs published in the FEDERAL REGISTER of December 10, 1964 (29 F.R. 16935) with respect to methyl bromide have been considered. These comments neither support nor oppose the specific proposal but relate to other petitions requesting tolerances for residues of inorganic bromides. No request having been received for referral of the proposal to an advisory committee: *It is ordered*, That the regulations for setting tolerances and granting exemptions from tolerances for pesticide chemicals in or on raw agricultural commodities (21 CFR 120.123) be amended by inserting immediately following the item "200 parts per million in or on almonds, • • •" a new item reading as follows:

§ 120.123 Inorganic bromides resulting from fumigation with methyl bromide; tolerances for residues.

• • • • •

200 parts per million in or on soybeans from use in accordance with the Plant Pest Control Program of the U.S. Department of Agriculture.

• • • • •

This action is taken pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(e), 68 Stat. 514; 21 U.S.C. 346a(e)) and delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90).

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201, written objections thereto, preferably in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 408(e), 68 Stat. 514; 21 U.S.C. 346a(e))

Dated: February 9, 1965.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 65-1630; Filed, Feb. 15, 1965; 8:48 a.m.]

Title 33—NAVIGATION AND NAVIGABLE WATERS

Chapter II—Corps of Engineers, Department of the Army

PART 207—NAVIGATION REGULATIONS

San Diego Harbor, Calif.

Pursuant to the provisions of section 7 of the River and Harbor Act of August 8, 1917 (40 Stat. 266; 33 U.S.C. 1), § 207.612 is hereby amended with respect to paragraph (a), subparagraph (1) (changing the description of the seadrome lights on the sealanes of the South Bay Seadrome, San Diego Harbor, Calif., effective 30 days after publication in the FEDERAL REGISTER, as follows:

§ 207.612 San Diego Harbor, Calif.; restricted areas.

(a) *The seaplane restricted area—(The area.* (1) • • •

(ii) The seaplane landing area will be marked by U.S. Standard Seadrome Lights, fixed amber on approach end of Sealane 9–27 and 14–32 and one row of fixed green center line lights on Sealane 14–32 only.

• • • • •

[Regs., January 29, 1965, 1507-32 (San Diego Harbor, Calif.)—ENGCW-ON]. (Sec. 7, 40 Stat. 266; 33 U.S.C. 1)

J. C. LAMBERT,
Major General, U.S. Army, The Adjutant General.

[F.R. Doc. 65-1608; Filed, Feb. 15, 1965; 8:46 a.m.]

Title 38—PENSIONS, BONUSES AND VETERANS' RELIEF

Chapter I—Veterans Administration

PART 3—ADJUDICATION

Subpart D—Waiver of Overpayment

OVERPAYMENTS, AND REVISION OF DECISIONS

1. In § 3.1902(b), subparagraph (10) is amended to read as follows:

§ 3.1902 Overpayments.

• • • • •

(b) • • •

(10) Amounts equal to amounts which have been refunded, and received by the

Fellows-Testagar Company
Detroit, Michigan
License No. [illegible]TB-678
July 23, 1965

592 NOTES

GENERAL INFORMATION

9. This was Reinspection No. 3 of this licensed program. The licensee was contacted by telephone on July 20, 1965, and arrangements were made to conduct this inspection on July 23, 1965.

10. Mr. V. E. Lavetter of the Industrial Hygiene Department, City of Detroit, was notified of this scheduled inspection and he accompanied the AEC representative during the inspection.

11. Mr. R. H. Carrigan, Vice-President of Fellows-Testagar, was interviewed. He provided the information given in these notes. Mr. Lavetter provided information concerning surveys which he had performed for the licensee.

INSPECTION HISTORY

12. The last previous inspection of this licensed program was conducted on February 7, 1963. As a result of that inspection the licensee was cited for two items of noncompliance. These were: (1) The licensee possessed greater than 100 pounds of thorium which was the maximum possession limit authorized by the license; (2) The storage of thorium was such that radiation levels in an unrestricted area exceeded the maximum permissible limits set forth in 10 CFR 20.105(b).

CORRECTION OF PREVIOUS ITEMS OF NONCOMPLIANCE

13. On April 11, 1963, the licensee sold 135 pounds of thorium oxalate and, therefore, reduced the total possession to less than 100 pounds of thorium which corrected the first item of noncompliance noted. The second item noted during the previous inspection was actually corrected at the time of the inspection by changing the storage location of the thorium oxalate.

PROGRAM

14. The licensee's program is unchanged since the time of the last previous inspection. Thorium is procured in the form of thorium oxalate. This material is heated in the presence of oxygen using nickel as a catalyst and is converted to thorium dioxide. Upon removal from the muffle furnace the thorium dioxide is put into an acid solution and stored for six months. At the end of six months the material is centrifuged to remove undesirable materials and is

PROGRAM, Cont'd.

14. then mixed with a preservative and the pH of the material is adjusted. The end product, Thorotrast, contains 25% thorium-dioxide and 25% dextrin. ~~The material is then placed in bottles, each which contains 25 cubic centimeters.~~

15. The thorotrast ~~is presently~~ is used as a colloidal x-ray contrast media. However, since the time of the last previous inspection, the U. S. Food and Drug Administration has required that this material be used only for experimental purposes in animals rather than in humans. Mr. Carrigan stated that because of this ruling the sale of the thorotrast has dropped off considerably. The last burning of 2.5 kilograms of thorium oxalate was conducted on October 5, 1964. Since that time the only work with the thorium has been the centrifuging and diluting of the ~~colloidal~~ thorium ~~thorium~~ dioxide. Records maintained by the licensee showed that this centrifuging and diluting operation involved twenty-five and a half hours of work within the preparation room during January, 1965 and eighteen and a half hours work in this room during June, 1965.

16. At the time of this inspection the licensee did not possess any thorium oxalate. The total amount of thorium dioxide on hand was about 45 pounds. Mr. Carrigan stated that he had ordered an additional fifty pounds of thorium oxalate, which was to be delivered in August of 1965.

ORGANIZATION AND ADMINISTRATIVE CONTROL

17. Mr. ~~Heindrich~~ J. J. Heinrick is the President of Fellows-Testagar Company. Mr. R. H. Carrigan is Vice-President of the Corporation and he is in charge of the Fellows-Testagar plant in Detroit. He also has the title of Chief Chemist. Mr. Carrigan assumes the entire responsibility of this licensed program.

18. Mr. Carrigan is also considered to be the Radiation Safety Officer. He directs the program in which the radioactive materials are used. He is in charge of maintenance of all records and is responsible for the safe handling of the radioactive materials.

19. There are three other persons who work for Mr. Carrigan who handle radioactive materials. Mr. R. Mazique, Manufacturing Pharmacist, is the prime operator. He has worked at Fellows-Testagar for approximately eight years. Mazique has been helped during loading and unloading operations of the furnace by Mrs. A. Collins and Mr. E. Bell. These are the same three individuals who were working

ORGANIZATION AND ADMINISTRATIVE CONTROL, Cont'd.

19. with the thorium at the time of the last previous inspection. Bell has not been employed with Testagar since April of 1965, however.

RADIOLOGICAL SAFETY PROCEDURES

20. Mr. Carrigan maintains copies of the source material license and copies of 10 CFR 40 and 10 CFR 20.

21. There are no written procedures concerning the safe handling of radioactive materials in this licensed program. It is a small operation and there is close working contact between those actually handling the material and Mr. Carrigan. Oral instructions and on-the-job training have been given to each of the individuals who has been working with the thorium.

22. Discussion with Mr. Carrigan revealed that the licensee has been using thorium according to the procedures that have been submitted with previous applications and letters to the Commission. These are referenced in Condition 8 of the source material license.

FACILITIES AND EQUIPMENT

23. The licensee is still doing work with thorium in the facility at 1354 West Lafayette, Detroit, Michigan. This building is within a condemned area for future road building within the City of Detroit. However, it will most likely be at least two years before the building is torn down and a new facility is ~~to be~~ constructed.

24. All thorium is handled within a restricted area. The initial calcining of the thorium oxalate and centrifuging of the thorium dioxide is done within the licensee's processing room. This room is kept locked by means of a padlock at all times when not in use. The key to this lock is maintained by Mr. Carrigan.

25. Immediately outside of the processing room is an area which the licensee terms as the anteroom. A row of storage cabinets along the south wall of this room is used for the storage of contaminated equipment and protective clothing. These cabinets also remain locked at all times. Fifty-five gallon drums located in this anteroom are used for the storage of waste material.

FACILITIES AND EQUIPMENT, Cont'd.

26. The licensee's processing room is contaminated and the licensee has made no attem to decontaminate this area. However, procedures have been established whereby protective clothing including boots, lab coats, gloves, and face masks are worn at all times while persons are doing work within the processing room. This equipment is all removed upon leaving the room and the area surrounding the processing room is scrubbed periodically. Mr. Carrigan stated that following each burning the anteroom is scrubbed down and the contaminated rags which result from this scrubbing are disposed of into the waste barrels.

27. During all operations within the processing room air is exhausted from the room by means of a window fan [redacted] at a height of about six feet above ground level into an adjacent parking lot. As indicated previously, each individual inside of the room wears a face mask. The masks used by these individuals are the Pulmosan Type 750 air masks. Each individual is responsible for replacing the filters and washing the masks after each use.

28. The licensee still possesses a Civil Defense Model V700 survey instrument which has a range of 0 - .5, 5, and 50 mr/hr. The incorporated check source is used to determine if the instrument is operating before surveys are conducted with this meter.

PERSONNEL MONITORING AND EXPOSURE DETERMINATION

29. Film badges are received by the licensee from the Nuclear Chicago Corporation on a weekly basis. The badges have been worn by Mazique, Collins, and Bell. However, since Bell left in April of '65, his badge has been assigned to a Mr. Wooden, maintenance man, who assists in decontaminating the area. Mr. Carrigan stated that R. Mazique wears his badge at all times. The other individuals wear their badges only when doing work around the processing room. All badges are sent in weekly whether or not they are used. The film badge records were reviewed from the beginning of 1963 through the week of June 28, 1965. There was no detectable exposure on any badge.

30. The licensee has also had a urinalysis program for the three individuals working with thorium. Urine samples were taken at six month intervals while the licensee was doing the calcining of the thorium oxalate. Five hundred milliliter samples of urine were taken on August 1, 1963, February 12, 1964, and June 16, 1964. These were analyzed by Controls for Radiation and all results showed less than 10 micrograms of thorium per liter of urine. This is apparently the minimum detectable level

RADIATION SURVEYS AND/OR EVALUATIONS

31. On April 2, 1963, samples for airborne thorium were taken by Mr. Lavetter of the City of Detroit for the licensee. The air samples were analyzed by the State of Michigan Public Health Department and the results of these analyses were sent back to Mr. Carrigan. In a letter dated December 17, 1964, to the Division of Materials Licensing, Mr. Carrigan recorded the results of the air survey and related this to his own 1964 production records to give an analysis of the airborne concentrations of thorium inside of the processing area and at the point of release into the uncontrolled area. A copy of this letter is included in our backup information.

32. At the time of this inspection and also in private conversation, Mr. V. Lavetter of the City of Detroit explained that the survey had been conducted using a Gelman air sampler with millipore filter paper. He stated that a known sample of thorium dioxide was taken from the licensee's processing room. This sample was weighed and distributed on millipore paper. It was then counted and relationship was obtained between counts per minute and the number of curies of thorium, (the curies or activity of thorium was obtained by using the specific activity and comparing with the known weight of the sample.) All counting was done with a GM tube having an end window whose thickness was 1.9 milligrams per square centimeter. The sample was placed approximately 2 centimeters from the GM tube. Following standardization of the counter by the method described above, the samples obtained were counted and the Health Department arrived at a given activity on the filter papers which were submitted to Mr. Carrigan and which were reported in the letter of December 17, 1964.

33. Production records maintained by Mr. Carrigan which were reviewed at the time of this inspection showed that during the year 1964, calcining was being done on a weekly basis for the period of January 13, 1964, through March 25, 1964, and again for the period September 21, 1964, through October 5, 1964. Based on these production records and the weekly number of hours involved, Mr. Carrigan calculated the total concentrations in the room in terms of hours-picocuries per milliliter-years. This figure was then compared with the maximum permissible concentration in terms of picocuries per milliliter averaged over the total number of working hours in a year. The comparison

RADIATION SURVEYS AND/OR EVALUATIONS, Cont'd.

33. here supposedly gives an indication of the average concentration to which individuals were exposed while working in the controlled area. This analysis by Mr. Carrigan is inadequate in two respects. First, the concentrations of thorium in the air were averaged over the total number of working hours in a year, while 10 CFR 20.103(b) specifies that concentrations must be averaged over periods of not greater than forty hours in any seven consecutive days. The licensee based this calculation on the total number of hours during which any particular process had taken place, rather than the total number of hours that each individual was exposed to concentrations of that level. It will further be noted ~~that the report given~~ in the letter dated December 17, 1964, submitted to DML that for the evaluation of the airborne concentrations in the uncontrolled area, the concentrations were averaged over 40 hours per week for fifty-two weeks per year. However, discussion with Mr. Carrigan revealed that the fan which exhausts air from the room is on only during periods where work is being carried out within the room and is not on a total ~~of~~ forty hours per week. Therefore, the licensee cannot use the forty hours per week as a dilution factor since no air was being pumped out of the room continuously during that ~~[redacted]~~ time. The licensee is therefore in noncompliance with 10 CFR 20.201(b) in that surveys and evaluations conducted ~~[redacted]~~ were inadequate in that air sample results were not based on actual individual working times, and they were averaged for periods of greater than forty hours; also, for the evaluation of airborne concentrations ~~[redacted]~~ pursuant to an uncontrolled area, the concentrations were averaged over forty hours per week times fifty-two weeks per year rather than being averaged ~~[redacted]~~ over actual fan on-times from the production room. (Note: In the letter dated December 17, 1964, Mr. Carrigan's allowed concentration limits which are given in terms of picocuries per milliliter are off by a factor of 10^{-6} from those given in the Regulations. It was also determined at the time of this inspection by conversation with Mr. Lavette and by review of his records that the numbers furnished by him to the licensee in terms of picocuries per milliliter were also off by a factor of 10^{-6}. Therefore, in calculating ratios between the allowable levels and the measured levels, the errors in each number cancelled each other out, and the ratios giv in that letter are correct based on the numbers that were used.)

POSTING AND LABELING

34. It was observed that the door leading to the processing room and the doors on the cabinets used for the storage of contaminated equipment were posted with signs in colors bearing the radiation caution symbol and the words "Caution - Radiation Area" and "Caution - Radioactive Materials."

35. The waste barrels sitting in the anteroom were also posted with signs in colors bearing the radiation caution symbol and the words "Caution - Radioactive Materials.

36. It was observed that the labels on each bottle containing the finished products, Thorotrast, bore the statements "A research tool for animal experimental use only." and "Warning: Not for administration to man. Not for administration to food-producing animals." This wording on the labels satisfies the requirements of the U. S. Food and Drug Administration and is in accordance with License Condition 9.

37. It was observed that Form AEC-3, "Notice to Employees," was posted on the door of the processing room.

WASTE DISPOSAL

38. Old contaminated clothing, cleaning rags, and broken equipment is stored in fifty-five gallon drums. When these are full, the licensee sends them to an authorized disposal agency. Since the time of the last inspection the licensee made one such shipment. This was on March 22, 1963, when three 55-gallon drums were sent to Nuclear Engineering, Inc.

INDEPENDENT MEASUREMENTS

39. A physical radiation survey was conducted by the AEC representative at the time of this inspection using an Eberline E-500B survey meter. The maximum radiation level found on the surface of the waste barrels and also near the door to the processing room was 0.5 mr/hr. Within the room itself, there were levels of up to 1.0 mr/hr, near the furnace and on the floor of the room; these readings were as the result of contamination within the room. Outside of the room a maximum level of 0.3 mr/hr was found on the surface of the grating covering the window fan.

INDEPENDENT MEASUREMENTS, Cont'd.

40. Dry smears were also taken at the time of this inspection and these were analyzed at Argonne National Laboratory. A copy of the report from ANL is attached as Exhibit A to this report. This shows that one smear of approximately 1 square foot area taken inside of the licensee's processing room showed almost 37,000 alpha disintegrations per minute. Other smears taken at various locations within the unrestricted area showed alpha counts ranging from about 100 to almost 800 disintegrations per minute. Mr. Carrigan was contacted by telephone on August 3, 1965, and informed of the results of these smears. He appeared somewhat surprised at the levels that were found outside of the room. He stated that they would mop down the area again to try to reduce these levels.

MANAGEMENT DISCUSSION

41. The deficiencies noted in the licensee's evaluation of airborne thorium were reviewed with Mr. Carrigan at the time of this inspection and again during a phone conversation on August 3, 1965. Mr. Carrigan stated that with regard to the airborne concentrations within the processing area he intended to take the following corrective action; First of all, no calcining of material is to be done until adequate equipment and facilities are installed to contain and reduce the concentrations of radioactive material. He stated that arrangements have been made with a contractor to come in and install a hood over the furnace used for the burning of the thorium oxalate. The hood will exhaust out of the roof of the building rather than out through the window. He stated that they intend to clean up the processing room such that only the hood itself would be contaminated. Mr. Lavetter of the City of Detroit is assisting in setting up and reviewing the plans for this hood facility. The licensee intends to purchase a Gelman air sampler. The licensee will contract some outside company to perform the analysis of the air samples. It is felt that additional dilution can be obtained by use of the hood. If the dilution is not adequate to reduce the concentrations to the allowable limits at the point of release, a filter system will be installed in the hood.

Exhibit A.

Norelius 654-1630

TYPE C

SPECIAL SERVICE
ALPHA, BETA, GAMMA MEASUREMENT

No. AE 178
Date 7-26-65

Please perform as a special service gross beta-gamma and alpha counting and recording for the samples listed hereon:

Control No.	Date Counted	Initials	Results d/m/sample	Suspected Contaminate	Identification
PTS-1024	7-28-65	[illegible]	α Blank	Co^{60}	Inside Containment Tele.. Physicians X-ray
			β 0		
PTS-1025			α Blank	Co^{60}	Outside surface Tel. - Physicians X-ray
			β Blank		TETRAD
PTS-1026			α 994	Th^{232}	Waste barrel surface
			β 516		
PTS-1027			α 5.50	Th^{232}	Floor of Ante room outside process area
			β Blank		
PTS-1028			α 36,923	Th^{232}	Floor inside door of containing room
			β 3,843		
PTS-1029			α 482	Th^{232}	Ante room window & ledge inside window
			β 263		
PTS-1030			α 98	Th^{232}	Outside wall
			β 133		

EXHIBIT A

8301 John C. Lodge Fwy.
Pavilion 7
Detroit, Michigan 48202

July 29, 1968

Mr. Richard H. Corrigan, Chief Chemist
Follows Pentagon-Division of
Follows Medical Mfg. Co., Inc.
1974 W. Lafayette
Detroit, Michigan 48216

Dear Mr. Corrigan:

This is to advise you that air samples collected by this writer in connection with the processing of [illegible] Chemium on July 18, 1968 did indicated the presence of [illegible] in concentration limits established by the U. S. Atomic Energy Commission and the Michigan Department of Public Health for both the [illegible] and the effluent from the chemist bench.

You are hereby directed to cease and desist from [illegible] further processing of any materials containing uranium. Such processing may not be resumed unless a satisfactory plan is submitted to and approved by this office, and properly implemented that adequate control of all toxicity and/or radioactivity is provided with such materials.

Yours very truly,

Victor L. Lavelle
Associate Industrial Hygienist
BUREAU OF INDUSTRIAL HYGIENE
872-1340, Ext. 292 or 293

VLL:jlp

cc: Mr. D. E. Van Farowe, Michigan Department of Public Health
Mr. Doyce H. Grier, Director, Region III Div. of Compliance
U. S. Atomic Energy Commission

DA# 68-3001

JUL 29 1968

DML:CEM
40-2407

APR 12 1965

Fellows - Testagar
Division of Fellows Medical
Manufacturing Company, Inc.
1354 West Lafayette
Detroit, Michigan 48226

Attention: Mr. Richard H. Carrigan
Vice President
Scientific Administration

Gentlemen:

Enclosed is Source Material License No. STB-678, as renewed. Please note that pursuant to Section 20.201, 10 CFR 20, copy enclosed, you are required to conduct such surveys as may be necessary to determine that you are in compliance with Part 20. This applies particularily, in your operations, to concentrations of airborne radioactivity to which employees are exposed and concentrations of radioactivity released to unrestricted areas. The frequency for conducting surveys should be based on the nature of the operations being performed and the results of previous surveys for similar operations.

Also, note that Condition 9 of this license requires that each container in which drug preparations containing thorium dioxide are packaged for transfer or for export shall display the same label as is required by the U. S. Food and Drug Administration under the Federal Food, Drug and Cosmetic Act. This condition was added to assure that all containers of drugs containing thorium dioxide which you transfer in intrastate commerce or export bear the FDA prescribed labeling and warnings regarding use of such drugs.

DISTRIBUTION:
Doc. Rm.
Br. & Div. rfs
Compliance Region III
Suppl.
N. Doulos, ML (3)
C. MacDonald, ML
State Health (Lic. only)

Very truly yours,

Donald A. Nussbaumer, Chief
Source and Special Nuclear Materials Branch
Division of Materials Licensing

Enclosures:
1. ~~STB-678, as renewed~~
2. 10 CFR 20

OFFICE ▶			ML	CGC	ML	REG
SURNAME ▶			DNussbaumer/jc	TBC	JMcBride	RLowenstein
DATE ▶			4/9/65	4/7	4/8/65	4/12/65

Form AEC-318 (Rev. 9-63) U. S. GOVERNMENT PRINTING OFFICE 16—62761-2

7905230150
P&R

UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

JAN [illegible]

DML:ND
IN REPLY REFER TO: 40-2407

Follows - Teslagar
Division of Follows Medical
Manufacturing Co., Inc.
1354 West Lafayette
Detroit, Michigan 48226

SUBJECT: NOTICE OF LICENSE EXPIRATION

Gentlemen: Attention: Mr. Richard H. Carrigan

Notice is given that Source Material License Number STB-678 expires on March 31, 1968.

If you desire to continue your program using source material(s), an application for renewal of the license should be filed with this office. It is to your advantage to file such an application at least thirty (30) days before the expiration date of your existing license. The application should be submitted using Form AEC-2, enclosed, in accordance with the instructions provided with the form. Your program will then be covered by your existing license until action is taken on your application for license renewal. (Title 10, Code of Federal Regulations, Part 40, Section 40.43(b). If an application is received less than 30 days prior to the expiration date of your license and cannot be processed before your existing license expires, this could result in your possessing source material without a valid license.

If you do not wish to renew your license, please complete the enclosed form "Certification of Status of Source Material Activities under United States Atomic Energy Commission Source Material License Number STB-678", and return it to this office.

If you have obtained an amendment which has extended the expiration date of the above license or if a new license has been issued which supersedes the above license, please disregard this notice.

This notice of your license expiration is sent for your convenience and it should not be interpreted that similar notices will be sent in the future. The responsibility for timely submission of an application for license renewal remains with the licensee.

Very truly yours,

Donald A. Nussbaumer

Donald A. Nussbaumer, Chief
Source & Special Nuclear Materials Branch
Division of Materials Licensing

Enclosures:
10 CFR, 20 & 40
Form AEC-2
"Certification . . ."

Dictator 12/22/67

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