

JUN 14 1990

Rosenblum, Goldenhersh, Silverstein
& Zafft, P.C.
ATTN: Richard E. Greenberg, Esq.
7777 Bonhomme Avenue
Fourteenth Floor
St. Louis, MO 63105

License No. 24-21362-01
General License 10 CFR 110.23
Docket No. 030-20567
EA 89-257

SUBJECT: SIXTH MODIFICATION TO ORDER SUSPENDING LICENSES

Gentlemen:

This refers to our Order Suspending Licenses (Order) issued January 11, 1990, as modified (following requests from American Radiolabeled Chemicals, Inc. (ARC)) in our letters dated February 26, March 2, March 12, April 9, and May 8, 1990 (Limited Modifications). This also refers to your letters dated April 3 and May 14, 1990.

In your April 3, 1990 letter, you requested further modification of the Order to authorize ARC to conduct the following: (1) purity checks; (2) repurification of inventory products; (3) purchase of licensed materials in larger quantities for subdivision; (4) change of solvents; and (5) the production of standards for quantitative autoradiography. The NRC reviewed that request and in a May 8, 1990, letter requested additional information on Items No. 1, 2, 4 and 5. Regarding Item No. 2, the NRC deferred a decision on that issue pending completion of a review of enforcement actions. In a letter dated May 14, 1990, ARC responded with the additional information requested in the NRC's May 8, 1990, letter.

We have reviewed your May 14, 1990, letter and have determined that sufficient information has been provided to further modify the Order to allow ARC to perform purity checks, to repurify inventory products, to change solvents and to produce standards for quantitative autoradiography.

Therefore, in accordance with the letters dated April 3 and May 14, 1990, and pursuant to Section IV of the January 11, 1990 Order Suspending Licenses, Section IV.A. of the Order is modified and shall read as follows:

"A. Receipt, repackaging, distribution, subdivision of licensed materials, decontamination of facilities, production of standards for autoradiography and purity checks, repurification, and changing solvents of inventory products under License No. 24-21362-01 and the licensee's general export license, granted pursuant to 10 CFR 110.23, are hereby authorized in accordance with this letter. Authority to conduct activities associated with the synthesis of radiolabeled compounds and receipt of non-prepackaged radiolabeled compounds remains suspended."

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& Zafft, P.C.

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All other provisions of the February 26, March 2, March 12, April 9, and May 8, 1990, Limited Modifications remain in effect.

As previously stated, your request to purchase larger quantities of licensed material will be considered after our review of enforcement options is completed.

If you have any questions regarding this matter, please contact Roy Caniano of my staff at (708) 790-5721.

Sincerely,

Original signed by
A. Bert Davis

A. Bert Davis
Regional Administrator

cc w/ltr dtd 04/03/90:
American Radiolabeled
Chemicals

PDR
SECY
CA

J. Taylor, EDO
H. T. Thompson, DEDS
J. Lieberman, OE
J. Johansen, OE
J. Goldberg, OGC
C. Woodhead, OGC
Enforcement Coordinators,
RI, RII, RIII, RIV, RV
F. Ingram, GPA/PH
B. Hayes, OI
D. Williams, OIG
E. Jordan, AEOD
EA File
Day File
DCS
J. Glenn, NMSS
R. E. Boyle, FAA/DOT
J. O'Connell, Jr., RSPA/DOT
State of Missouri
E. Horn, U. S. Customs

RIII
Shear/Id

RIII
Caniano

RIII
Mallett

RIII
Berson

RIII
Grobe

RIII
Marelius

RIII
Papertello

RIII
Davis

NMSS
Gls for
for Steve
Glenn
via telecon
on 5/29/90

OGC
Gls for
RSC for
Lewis
via telecon
on 5/24 and
5/30

Copy of modification and letters
faxed to HQ (RSC and NMSS) for review

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April 3, 1990

Mr. Bruce Berson
Regional Attorney
U. S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Re: American Radiolabeled Chemicals, Inc.

Dear Bruce:

This is to request additional interim relief on behalf of American Radiolabeled Chemicals, Inc. ("ARC") during the period of the suspension and while the Commission reviews its enforcement options following the enforcement conference held on April 4, 1990. While ARC is hopeful that the Commission will permit full resumption of production in the near future, ARC is requesting this relief in order that ARC can continue with certain of its operations while the Commission decides on a final enforcement position. In order to avoid repeated requests if there is a substantial delay before the Commission reaches a final decision, we are requesting authorization for the following multiple procedures:

1. Purity Checks: ARC requests authorization to conduct purity checks on products in its inventory. This will entail applying 0.1 uCi of a carbon 14 compound and 20 uCi of a tritium labeled compound on a strip of paper or TLC plate and then running the product in a suitable solvent system and scanning with a radiochromatogram scanner.

2. Repurification of Inventory Products: If the results of the quality control analysis indicate certain products to be impure, ARC requests authorization to purify the products for sale. The purification procedure will entail preparative paper or thin layer chromatography.

3. Buying Licensed Materials in Larger Quantities for Subdivision: It is more economical for ARC to purchase products in bulk and subdivide them into smaller amounts than buying prepackaged materials in small amounts. Protocol to be used for handling subdivision would be the same as that being used to subdivide products already in inventory and would be limited to

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Mr. Bruce Berson
April 3, 1990
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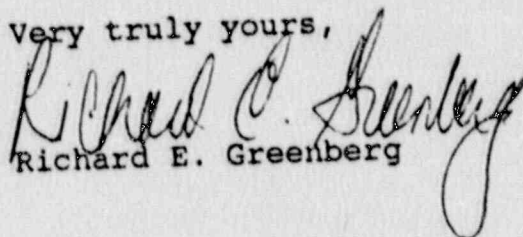
the non-volatile materials previously authorized.

4. Changing Solvents: Products offered through ARC catalog are packaged in several solvents, such as sterile water, sterile saline, ethanol, etc. However, ARC does not store all the products in all the solvents mentioned in our catalog. Since most of our customers are medical doctors who do not have the facilities or knowledge to convert products from one solvent to another, the customers frequently specify the particular solvent dictated by their research. This will require removing solvent under vacuum and redissolving the product into the solvent desired.

5. Standards for Quantitative Autoradiography: This is our exclusive product line, and many researchers worldwide rely on a continuous supply of these standards. The protocol requires making a plastic solution containing carbon 14 or tritium in extremely small concentrations, usually a few microcuries per gram of plastic. The plastic solution is solidified and cut into 10 micron thick pieces which are mounted on a microscope slide or cover glass with water.

Please do not hesitate to contact ARC or Don Soldan if the Commission needs additional information regarding the activities subject to this request. Although ARC is hereby asking for authorization for additional procedures, performance of these procedures will be subject to the same constraints and controls under which ARC is currently being permitted to operate on an interim basis.

Very truly yours,


Richard E. Greenberg

REG/dat

cc: American Radiolabeled Chemicals, Inc.
(Personal and Confidential)

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