

UNITED STATES
NUCLEAR REGULATORY COMMISSION

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|----------------------------|---|-------------------------|
| In the Matter of |) | |
| |) | Docket No. 030-37503 |
| Brogan Pharmaceuticals |) | License No. 13-32662-01 |
| 1195 Arrowhead Court |) | |
| Crown Point, IN 46307-8222 |) | |

ORDER REVOKING LICENSE FOLLOWING
30-DAY SUSPENSION (EFFECTIVE IMMEDIATELY)

I

Brogan Pharmaceuticals (Licensee) is the holder of Materials License No. 13-32662-01, issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to the Atomic Energy Act of 1954, as amended, that authorizes the activities stated therein. The license has an expiration date of August 31, 2017.

II

Pursuant to 10 CFR 171.16, the Licensee is required to pay an annual fee for this license. The Licensee's annual fee for License No. 13-32662-01 for Fiscal Year 2008, as set forth in fee categories 3M & 3P of 10 CFR 171.16(d), is \$1,000.00. In accordance with 10 CFR Part 15, the Licensee was sent an original invoice dated August 4, 2008, and a second notice dated November 20, 2008, requesting payment. The second notice of payment due specifically informed the Licensee that nonpayment of the fee may result in the suspension or revocation of the license in accordance with the enforcement provisions of the Commission's regulations, namely, 10 CFR 171.23. To date, the annual fee(s) have not been paid as required by 10 CFR Part 171. This Order suspends License No. 13-32662-01, as explained below. If the fee and any other delinquent debts to NRC are paid within 30 days from the date of this Order, this Order

will be withdrawn and the Licensee will be permitted to resume operations under License No. 13-32662-01, if all other requirements are met. If the Licensee does not pay all debts within 30 days from the date of this Order, the license will be revoked by the terms of this Order and the Licensee will, in the future, not be able to operate under License No. 13-32662-01. If the former Licensee wants to resume operations after revocation of the license, the former Licensee will have to pay all debts to NRC and apply for and be issued a new license.

III

I have concluded that the Licensee has willfully violated NRC requirements. In addition, prior notice of the violation and an opportunity to achieve compliance were provided. Therefore, pursuant to 10 CFR 2.202, I find that the violation requires that this Order be immediately effective. In view of the foregoing and pursuant to Sections 81, 161b, 161c, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 170.41, 171.23, and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

- A. License No. 13-32662-01 is suspended for 30 days from the date of this Order with respect to receipt and use of licensed nuclear materials. If, within this 30-day period, the Licensee does not pay all debts due to NRC, the license will automatically be revoked, effective 30 days from the date of this Order. During the time that the license is suspended, and after license revocation, the license remains in effect, pursuant to 10 CFR 30.36, with respect to the possession, transfer, and storage of licensed nuclear material remaining in the Licensee's possession, as contamination or in other forms, until the Commission notifies the Licensee in writing that the license is terminated.

- B. Until notified by the Commission in writing that the license is terminated, the Licensee shall:
1. restrict activity involving licensed nuclear material to decommissioning and safe, secure storage or transfer of material; and
 2. continue to control entry into restricted areas until the Licensee has determined and NRC has confirmed that such areas are suitable for release in accordance with NRC requirements.
- C. Unless full payment is made, the Licensee shall, within 30 days from the date of this Order, arrange for disposal or transfer to an authorized recipient of any licensed nuclear material acquired or possessed under the authority of License No. 13-32662-01 and shall take all actions required by 10 CFR 30.36. Such disposal must take place within 60 days from the date of this Order.
- D. Within 5 days after disposal of the material, the Licensee shall notify, in writing, the Director, Division of Nuclear Materials Safety, for NRC Region III, at 2443 Warrenville Rd, Suite 210, Lisle, IL 60532-4352, of the disposition of all licensed nuclear material acquired or possessed under the authority of License No. 13-32662-01, including in the written notice details as to how, where, and when disposition of the material took place.
- E. Within 30 days from the date of this Order, if the Licensee manufactures, distributes, or provides services to other licensees, the Licensee must notify, in writing, each customer or client that authorization to provide any of these services has been suspended. Furthermore, the Licensee must notify its customers and clients that they may need to amend their licenses to be in compliance with NRC requirements if their license

specifically states reliance on the service of the Licensee. The Licensee must provide the Director, Division of Nuclear Materials Safety, for NRC Region III at 2443 Warrenville Rd, Suite 210, Lisle, IL 60532-4352 evidence of the notification and a list of customers or clients notified.

- F. Within 65 days from the date of this Order, the Licensee shall conduct a final radiation survey of the premises where the licensed activities were carried out, pursuant to 30.36(j), and submit a written report of the results of this survey to the Director, Division of Nuclear Materials Safety, for NRC Region III, 2443 Warrenville Rd, Suite 210, Lisle, IL 60532-4352.
- G. Within 30 days from the date of this Order, the Licensee shall submit a written report to the Director, Division of Nuclear Materials Safety, for NRC Region III, 2443 Warrenville Rd, Suite 210, Lisle, IL 60532-4352 that includes: (1) a listing of all materials disposed of, transferred, or still in the possession of the Licensee, (2) a description of the conditions of storage of retained material and actions being taken to control access to the material, and (3) for any material not disposed of or transferred, a description of the actions taken to attempt to dispose of or transfer the material and why those actions were unsuccessful.
- H. The license shall be terminated upon satisfaction of the requirements of 10 CFR 30.36.
- I. After the license is revoked, the former Licensee may not resume previously-licensed operations until:
 - 1. The former Licensee has applied for and been issued a new license under 10 CFR Part 30; and
 - 2. All debts to NRC, including the fee for the new license, have been paid in full.

The Chief Financial Officer may relax or rescind, in writing, any of the above conditions upon a showing by the Licensee of good cause. A request for modification of the above conditions shall be submitted to the Chief Financial Officer, with a copy to the Director, Division of Nuclear Materials Safety, NRC Region III, in writing and under oath or affirmation and must be received within 30 days from the date of this Order.

IV

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, within 30 days of its issuance. In addition, the Licensee and any other persons adversely affected by this Order may request a hearing on this Order within 30 days its issuance.

Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Chief Financial Officer, and include a statement of good cause for the extension.

The answer shall be in writing and under oath or affirmation, and shall specifically admit or deny each allegation or charge made in this Order. The answer shall set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why this Order should not have been issued. Any answer shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Rulemakings and Adjudications Staff, Washington, DC 20555. Copies shall also be sent to the Chief Financial Officer, U.S. Nuclear

Regulatory Commission, Washington, DC 20555; the Assistant General Counsel for Materials Litigation and Enforcement at the same address; the Regional Administrator, NRC Region III, 2443 Warrenville Rd, Suite 210, Lisle, IL 60532-4352; and to the Licensee if the answer is by a person other than the Licensee.

If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If the Licensee or a person whose interest is adversely affected requests a hearing, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(I), the Licensee may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error. The motion must state with particularity the reasons why the order is not based on adequate evidence, and must be accompanied by affidavits or other evidence relied on.

A request for hearing or to set aside the immediate effectiveness of this Order must be filed in accordance with the NRC E-Filing rule, which became effective on October 15, 2007. The NRC E-filing Final Rule was issued on August 28, 2007, (72 Fed. Reg. 49,139) and codified in pertinent part at 10 CFR Part 2, Subpart B. The E-Filing process requires participants to submit and serve documents over the internet or, in some cases, to mail copies on electronic optical storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements associated with E-Filing, at least five (5) days prior to the filing deadline the requestor must contact the Office of the Secretary by e-mail at HEARINGDOCKET@NRC.GOV, or by calling (301) 415-1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any NRC proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances when the requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at <http://www.nrc.gov/site-help/e-submittals/install-viewer.html>. Information about applying for a digital ID certificate also is available on NRC's public website at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>.

Once a requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for a hearing through EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public website at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the filer submits its document through EIE. To be timely, electronic filings must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon

receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request is filed so that they may obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the "Contact Us" link located on the NRC website at <http://www.nrc.gov/site-help/e-submittals.html> or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397-4209 or locally, (301) 415-4737.

Participants who believe that they have good cause for not submitting documents electronically must file a motion, in accordance with 10 C.F.R. 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at http://ehd.nrc.gov/EHD_Proceeding/home.asp, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, Participants are requested not to include copyrighted materials in their works.

V

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, this Order shall be final 30 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Part III shall be final when the extension expires if a hearing request has not been received. AN ANSWER OR REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

VI

In lieu of filing an answer to the Order, the Licensee may pay the total amount specified below. This amount must be received by the Office of the Chief Financial Officer within 30 days from the date of this Order. This Order is withdrawn if, within 30 days from the date of this Order, the Office of the Chief Financial Officer receives the total amount specified below:

| <u>Amount Due</u> | | | | |
|---------------------|-----------------------|----------------------|-------------------------|-------------------|
| <u>Invoice Date</u> | <u>Invoice Number</u> | <u>Amount Billed</u> | <u>Late Charges Due</u> | <u>Amount Due</u> |
| 1. August 04, 2008 | AM3810-08 | \$1,000.00 | \$317.48 | <u>\$1,317.48</u> |
| Total Amount: | | | | \$1,317.48 |

The total amount listed above is a delinquent debt to the United States. Failure to pay the total amount within 30 days from the date of this Order may, pursuant to 10 CFR Part 15, result in referral of the delinquent debt to a collection agency, referral to the U.S. Department of Treasury or the U.S. Department of Justice for collection, or other action deemed appropriate.

PLEASE KEEP THIS COVER SHEET WITH THIS ORDER. THANKS!

DOCUMENT NAME: [G:\DFM\ART\Orders\AM3810-08.wpd](#)

ORIGINATOR: R. SKINKER

SUBJECT: ORDER REVOKING [BROGAN PHARMACEUTICALS](#)
LICENSE NO. [13-32662-01](#)

*******ROUTING LIST*******

| | <u>NAME</u> | <u>DATE</u> |
|----|-----------------------------|-------------|
| 1. | <u>M. WILLIAMS, DFM/LFT</u> | _____ |
| 2. | <u>S. REYNOLDS, RIII</u> | _____ |
| 3. | <u>C. MARCO, OGC</u> | _____ |
| 4. | <u>T. GRANCORVITZ, DFM</u> | _____ |
| 5. | <u>C. RHEAUME, DFM</u> | _____ |
| 6. | <u>M. BROWN, DCFO</u> | _____ |
| 7. | <u>J. E. DYER, CFO</u> | _____ |

PLEASE RETURN DOCUMENT TO RICHARD SKINKER,
MAIL STOP, T9-E10

CERTIFIED RETURN RECEIPT REQUESTED
COPY OF NRC FORM 47

Ready for dispatching yes ___ no ___