

# New Mexico Regulation and Licensing Department BOARDS AND COMMISSIONS DIVISION

**Board of Pharmacy** 

5500 San Antonio Drive NE, Suite C, Albuquerque, NM 87109 (505) 222-9830 • Fax (505) 222-9845 • (800) 565-9102 http://www.rld.state.nm.us/boards/pharmacy.aspx

## Outsourcing Facility Application Self-Assessment Form

The Pharmacist-In-Charge\* is responsible for completing this self-assessment form. Please check the correct answer. Return the completed form.

# ENSURE CORRECT ATTESTATION(S) ARE SIGNED

- Has any State Licensing or Disciplinary Board or comparable body in the Armed Service, denied your application for licensure, reinstatement or renewal, or taken any action against your license, including, but not limited to reprimand, suspension, or revocation (license of Pharmacist-In-Charge and/or facility), since your last renewal (if applicable)?
  Y D N If yes, explain and attach a copy of the relevant document(s).
- 2. Do you distribute or dispense controlled substances into New Mexico? □ Y □ N
  A. If yes, do you have a current NM State Controlled Substance registration? □ Y □ N
  License #: CS
  Expiration Date:
- 3. Does your facility compound non-patient specific product for distribution into NM?
  - A. Are you compliant with current good manufacturing practices (cGMP) requirements?  $\Box$  Y  $\Box$  N
  - **B.** Are products labeled correctly per NMAC 16.19.37.10 (D)? □ Y □ N
  - **C.** Do you operate in compliance with NMAC 16.19.37?  $\Box$  **Y**  $\Box$  **N**
- 4. Does your facility compound patient specific preparations for dispensing to NM residents?  $\Box$  Y  $\Box$  N
  - A. If yes you must first be registered with the NMBOP as a Pharmacy (NMBOP license # PH\_\_\_\_\_)
  - **B**. Are you compliant with cGMP requirements?  $\Box$  **Y**  $\Box$  **N**
  - C. Are products only labeled for use on a specific patient?  $\Box$  Y  $\Box$  N

If you would like to make any written comments about the content on the form, please write on the back of this form or attach a separate sheet of paper.

# Attestation of truthful information provided and compliance with laws and regulations: (QUESTIONS 1, 2, 3)

The registrant/licensee operates in compliance with 503B requirements including cGMP. Non patient-specific products are not sold for resale. The registrant/licensee operates in compliance with NM Board of Pharmacy regulations, as applicable. I (we) attest under penalty of perjury that the information given on this form is true and accurate.

## SIGNATURE-PHARMACIST-IN-CHARGE [\*Pharmacist-In-Charge per NMAC 16.19.37.7 (K)]

### PRINTED NAME-PHARMACIST-IN-CHARGE

#### PHONE NUMBER & E-MAIL

### <u>Attestation of truthful information provided and compliance with laws and regulations:</u> (QUESTION 4)

**Producers of patient-specific preparation**(s): The registrant/licensee operates in compliance with cGMP requirements, and only dispenses medication pursuant to a valid prescription as defined in NMSA 61-11-2(CC). The registrant/licensee operates in compliance with NM Board of Pharmacy regulations, as applicable. I (we) attest under penalty of perjury that the information given on this form is true and accurate.

DATE