CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205029Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

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1.3.5.2 Patent certification - updated 7 March 2013

In accordance with Section 21 CFR 314.50(i)(1) Belcher Pharmaceuticals, LLC (Belcher) makes the following Patent Certification for (b) (4) proposed trade name (epinephrine injection, USP 1:1000 [mg/mL]):

As part of this NDA (205029), Belcher references listed drug data contained in CorePharma, LLC's NDA (20800) pertaining to Twinject, an approved epinephrine (0.3 mg/mL) product for use in the emergency treatment of severe allergic reactions.

There is one method of manufacturing patent that applies to the production of the active pharmaceutical ingredient, i.e., epinephrine. Paragraph (i)(1)(iii)(2) of 21 CFR 314.50 states that "an applicant is not required to make a certification with respect to any patent that claims only a method of manufacturing the drug product for which the applicant is seeking approval." As such, no patent certification for this method of manufacturing patent has been made.

On October 31, 2012, Belcher had certified that there were no relevant patents related to Twinject or Belcher's proposed epinephrine product for use in septic shock.

On February 20, 2013, the Agency sent Belcher an information request for patent certification on two unexpired patents, 7297136 and 7621891, associated with Twinject (NDA 20800), as listed in the Orange Book. Belcher now makes such paragraph IV patent certification per the Agency's request in accordance with 21 CFR 314.50(i)(1)(i)(A)(4).

Belcher's proposed epinephrine drug product will be supplied in ampoules made available for continuous intravenous infusion upon dilution and does not include a delivery device. Both patents 7297136 and 7621891 consist of apparatus claims only for an injector device (i.e., autoinjector) for delivery of one or two doses. Patent 7297136 does not claim delivery of epinephrine. Patent 7621891, which is a continuation-in-part of patent 7297136, does claim delivery of epinephrine by this particular autoinjector. Belcher's proposed drug product does not consist of such a pre-filled injector device intended for self-administration. Therefore, Belcher's proposed epinephrine drug product will not infringe on device patents 7297136 and 7621891.

Paragraph IV Certification

I, Mihir Taneja of Belcher Pharmaceuticals, LLC, certify that Patent No. 7297136 and Patent No. 7621891 will not be infringed by the manufacture, use, or sale of (b) (4) (epinephrine injection, USP 1:1000 [mg/mL]) for which this application is submitted.

To this effect, I and Belcher have complied with the requirements under 314.52(a) with respect to providing a notice to each owner of the patent or their representatives and to the holder of the approved application for the drug product which is claimed by the patent or a use of which is claimed by the patent and with the requirements under 314.52(c) with respect to the content of the notice. These notices were sent out on February 27, 2013.

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Delivery receipts for each of these notices, sent to the following, are attached:

- Owner of Patents 7,621,891 and 7,297,136:
  Ron Wyrick, President
  Washington Biotech Corporation
  4503 E Red Roan Drive
  Spokane, WA 99217-9734
- Holder of Twinject NDA 20800:
  Amedra Pharmaceuticals LLC
  Christopher Worrell, CEO
  2 Walnut Grove Dr., Suite 190
  Horsham, PA 19044-7707

Sincerely,

Mihir Taneja
Vice President
Belcher Pharmaceuticals, LLC
6911 Bryan Dairy Road
Largo, FL 33777
(727) 471-0850
mihirt@belcherpharma.com

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1.3.5.2 Patent certification - updated 4 March 2013

In accordance with Section 21 CFR 314.50(i)(i)(1) Belcher Pharmaceuticals, LLC (Belcher) makes the following Patent Certification for [redacted] (b) (4) proposed trade name (epinephrine injection, USP 1:1000 [mg/mL]):

As part of this NDA (205029), Belcher references listed drug data contained in CorePharma, LLC's NDA (20800) pertaining to Twinject, an approved epinephrine (0.3 mg/mL) product for use in the emergency treatment of severe allergic reactions.

There is one method of manufacturing patent that applies to the production of the active pharmaceutical ingredient, i.e., epinephrine. Paragraph (i)(1)(iii)(2) of 21 CFR 314.50 states that "an applicant is not required to make a certification with respect to any patent that claims only a method of manufacturing the drug product for which the applicant is seeking approval." As such, no patent certification for this method of manufacturing patent has been made.

On October 31, 2012, Belcher had certified that there were no relevant patents related to Twinject or Belcher's proposed epinephrine product for use in septic shock.

On February 20, 2013, the Agency sent Belcher an information request for patent certification on two unexpired patents, 7297136 and 7621891, associated with Twinject (NDA 20800), as listed in the Orange Book. Belcher now makes such patent certifications per the Agency's request in accordance with 21 CFR 314.50, paragraph (i)(i)(4).

Belcher's proposed epinephrine drug product will be supplied in ampoules made available for continuous intravenous infusion upon dilution and does not include a delivery device. Both patents 7297136 and 7621891 consist of apparatus claims only for an injector device (i.e., autoinjector) for delivery of one or two doses. Patent 7297136 does not claim delivery of epinephrine. Patent 7621891, which is a continuation-in-part of patent 7297136, does claim delivery of epinephrine by this particular autoinjector. Belcher's proposed drug product does not consist of such a pre-filled injector device intended for self-administration. Therefore, Belcher's proposed epinephrine drug product will not infringe on device patents 7297136 and 7621891.

I, Mihir Taneja of Belcher Pharmaceuticals, LLC, certify that Patent No. 7297136 and Patent No. 7621891 will not be infringed by the manufacture, use, or sale of [redacted] (b) (4) (epinephrine injection, USP 1:1000 [mg/mL]) for which this application is submitted.

To this effect, I and Belcher have complied with the requirements under 314.52(a) with respect to providing a notice to each owner of the patent or their representatives and to the holder of the approved application for the drug product which is claimed by the patent or a use of which is claimed by the patent and with the requirements under 314.52(c) with respect to the content of the notice. These notices were sent out on February 27, 2013.

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- Holder of Twinject NDA 20800:
  Amedra Pharmaceuticals LLC
  Christopher Worrell, CEO
  2 Walnut Grove Dr., Suite 190
  Horsham, PA 19044-7707

Sincerely,

Mihir Taneja
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