Medical Products Agency

Report No: ***6.2.1-2015-103399***

STATEMENT OF NON-COMPLIANCE WITH GMP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer [1]

Part 1

Issued following an inspection in accordance with :
Art. 111(7) of Directive 2001/83/EC as amended
Art. 15 of Directive 2001/20/EC

The competent authority of Sweden confirms the following:
The manufacturer: ***Bend Research Inc.***
Site address: ***20503 Builders Street, 64550 Research Road, Bend, Oregon, 97701, United States***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-02-24*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC

[1] *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and 80(7) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

Part 2

Human Medicinal Products
Human Investigational Medicinal Products

1 NON-COMPLIANT MANUFACTURING OPERATIONS

Include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets 1.2.1.17 Other: Spray dried intermediates(en)
1.5	**Packaging**
	1.5.2 Secondary packing
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: Spray dried intermediates(en)
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Part 3

1. Nature of non-compliance:

Repeated inspections with unacceptable level of GMP-compliance. Repeated failures to correct deficiencies and to provide requested and reliable information. During the last inspection (Feb 2016), 2 critical, 7 major and 12 other deficiencies were found. The two critical and one major deficiency concerns data integrity. Major deficiencies were also found in the areas of: Validation, Hygiene routines, Identification of mobile equipment in the multipurpose facilities, Documentation routines. Several findings from the two previous MPA inspections Aug-Sep 2015 and in Aug 2012 had not been corrected.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. 5.9.1-2015-071301

The last valid EU-GMP certificate (No. 5.9.1-2015-071301) for the IMP production issued by MPA Sweden (expired in August 2015) will be withdrawn. It is recommended that, unless exceptionally justified, any pending Clinical Trial Applications in the EEA, listing Bend Research Inc (BRI) as a manufacturer, are not approved until a new GMP certificate has been issued. No new EEA marketing authorisation applications, line extensions or variations to existing EU marketing authorisation applications where BRI is involved as a manufacturer can be supported until a new GMP certificate has been issued. These recommendations are not meant to interfere with the possibility of making exceptions for critical supply of a medically essential product (whether as a marketed product or as part of an ongoing clinical trial). If there is a significant patient risk connected to discontinuation of a treatment and no alternative

treatment exists, the supply may be regarded as medically essential but this should be verified with the competent authority in the country concerned.

Recall of batches already released
No recall of batches has been deemed necessary to date.

Teleconference Date	2016-05-04	**Teleconference Time (CET)**	NA	**Dial in no.**	NA

2016-05-16

Name and signature of the authorised person of the Competent Authority of Sweden

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