Department
for Environment
Food & Rural Affairs

Nobel House
17 Smith Square
London SW1P 3JR

T 08459 335577
helpline@defra.gsi.gov.uk
www.defra.gov.uk

Bavarian Nordic, Inc.
2425 Garcia Avenue
Mountain View, CA 94043
USA

Our ref: 11/R44/01
9 December 2014

From Lord de Mauley
Parliamentary Under Secretary

ENVIRONMENTAL PROTECTION ACT 1990, SECTIONS 111 AND 112: CONSENT TO RELEASE GENETICALLY MODIFIED ORGANISMS

1. On 8 January 2012 the Secretary of State issued a consent to BN ImmunoTherapeutics Inc. (now named Bavarian Nordic Inc.) in accordance with its application ref. 11/R44/01 to release genetically modified organisms, subject to the conditions set out in Schedule 1 to that consent. A variation to this consent was issued on 10 December 2012 with a condition omitted in Schedule 1 and a further variation was issued on 16 November 2013 so that the date for completion of patient enrolment was amended to December 2014.

2. I am writing to give notice pursuant to Section 111(10) of the Environmental Protection Act 1990, that the conditions of the above-mentioned consent are varied so that under Condition 1 the date for the completion of patient treatment is included and shown as August 2015. The revised Schedule 1 to the letter of consent is attached. I note that Bavarian Nordic Inc. has requested this variation.

3. Insofar as they relate to the protection of human health and safety, the terms and conditions of this variation to the consent have been agreed with the Health and Safety Executive.

LORD DE MAULEY

Schedule 1 to Consent to release Genetically Modified Organisms
Application Reference 11/R44/01

LIMITATIONS AND CONDITIONS

Condition 1. The holder of the consent must perform the release in accordance with the information provided in application ref 11/R44/01 dated 22 September 2011 and reproduced in Schedule 2, except that the date for completion of patient enrolment, as set out in the application, should be read as December 2014. The date for completion of patient treatment is August 2015.

Condition 2. In addition to the general condition specified in section 112(5)(b) of the Environmental Protection Act 1990, as amended by regulation 29 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (the 2002 Regulations), the holder of the consent must submit:

(1) a report to the Secretary of State of any adverse effects to the subjects that were not anticipated at the time the environmental risk assessment was conducted, within 72 hours of that adverse effect being discovered; and

(2) a report to the Secretary of State within 3 months of the date of administration of the last dose of the GMO which includes the following:

(i) information on any adverse effects to the subjects that were not anticipated at the time the environmental risk assessment was conducted;

(ii) an account of how risks that were identified in the environmental risk assessment were managed during the trial; and

(iii) information on whether there was any deviation from the proposed trial plan reproduced in Schedule 2.

Condition 3. The holder of the consent will consider each site individually, and put in place localised guidelines based on the site's existing mechanisms for dealing with needle stick injuries and the disposal of GMO waste.

EXPLANATORY MEMORANDUM

This memorandum explains but does not form part of the consent. It contains important information on the general conditions and other provisions to which the consent is subject.

Schedule 1

Schedule 1 to the consent sets out the limitations and conditions which are relevant to the particular release applied for.

Condition 1 sets out the scope of the release authorised by the consent. It includes everything set out in the application for consent.

Condition 2 specifies the information and time which the consent holder is required to notify to the Secretary of State in particular circumstances.

General conditions and other provisions to which the consent is subject.

Certain general conditions are implied in every consent for the release of genetically modified organisms. These conditions are set out in section 112(5) of the Environmental Protection Act 1990 and are summarised below.

Subject to the extent and manner of the release authorised by the consent and any particular limitations or conditions specified in the Schedule, the holder of the consent is required:

a. to take all reasonable steps to keep himself informed (by reference to the nature of the organisms and the extent and manner of the release) of any risks there are of damage to the environment being caused as a result of their being released (section 112(5)(a));

Note: Condition a. makes consent holders responsible for keeping themselves informed (e.g. by appropriate monitoring) of any risks to the environment which may arise at any time after the release has been carried out.

b. to notify the Secretary of State forthwith of -

i) any new information which becomes available with regard to any risks there are of damage to the environment being so caused, and

ii) any unforeseen event, occurring in connection with a release by him, which might affect the risks there are of damage to the environment being caused as a result of their being released (section 112(5)(b) as inserted by regulation 29(3)(a) of the 2002 Regulations);

Note: Condition b.(i) requires consent holders to notify the Secretary of State of any new information about the risks which becomes available. Condition b.(ii) is, in effect, a requirement for the consent holder to report to the Secretary of State on the outcome of the release and any unforeseen event(s), particularly in relation to any proposals to conduct further related work which may result in the marketing of a product.

c. to take such measures as are necessary to prevent damage to the environment being caused as a result of the release or, as the case may be, the marketing of the organisms (section 112(5)(c) as substituted by regulation 29(3)(b) of the 2002 Regulations); and

d. notify the Secretary of State of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in paragraph (b)(ii) above (section 112(5)(d) as substituted by regulation 29(3)(c) of the 2002 Regulations); and

e. in a case where new information becomes available or an unforeseen event so occurs, revise the information contained in his application for a consent accordingly and supply the revised information to the Secretary of State(section 112(5)(e) as substituted by Regulation 29(3)(c) of the 2002 Regulations);

f. to take all reasonable steps to keep himself informed of developments in the techniques which may be available in his case for preventing damage to the environment being caused as a result of the release (section 112(7)(a)); and

g. to notify the Secretary of State forthwith if it appears at any time that any better techniques are available than is required by any of the conditions listed in the Schedule to the consent (section 112(7)(b)).

Note: conditions c. d. e. f. and g. are all designed to ensure that the consent holder uses best available techniques not entailing excessive cost (BATNEEC) to control the effects of the release in relation to the protection of the environment, to inform the Secretary of State of those changes and to supply a revised copy of the application. If better techniques become available than those implied by the consent conditions specified in the Schedule, the conditions attached to the consent may be varied as appropriate.

Under section 111(10) of the 1990 Act, any consent granted by the Secretary of State may be revoked or varied:

The Secretary of State may at any time, by notice given to the holder of the consent, revoke the consent or vary the consent (whether by attaching new limitations and conditions or by revoking or varying any limitations and conditions to which it is at that time subject).

Note: revocation or variation of a consent may be as the result of enforcement action, but is more likely to arise following information notified to the Secretary of State under the terms of the consent (e.g. after the completion of a particular stage in a programme of work and before proceeding to the next stage).