TORPAC®
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*Special Capsules * Capsule Machinery * Soluble Containers*

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A Review of European Union Regulations Permitting Torpac Porcine Gelatin Capsules To Be Used In Products For Food Producing Animals in the EU.

The purpose of this letter is to summarize the key EU Regulations that permit Torpac Veterinary Size Porcine Gelatin Capsules to be used in Food Producing Animals (including ruminants) in the EU. The regulations permitting use in registered medicines are very clear. The regulations permitting use in animal feeds including nutritional products are equally clear but require an understanding of the derogations (exemptions) for gelatin from non-ruminants and hide or skin.

As background, Torpac Veterinary Size Porcine Gelatin Capsules are made only from porcine gelatin derived from the skin of pigs. There are no other animal derived ingredients in our capsules. The porcine gelatin we use is manufactured in the USA, Canada or European Union at government inspected factories. Government veterinary officials certify every lot of gelatin we use and every batch of capsules we produce. We maintain full traceability from final product to raw materials in compliance with government regulations, ISO 9001 and HACCP.

Capsules For Registered Medicines.

EMEA Center For Veterinary Medicinal Products has issued two guidance notes **EMEA/CVMP/145/97R** effective 17 June 1999 and **EMEA/410/01-Rev 2** effective 1 July 2004 that is only applicable to gelatin derived from ruminant animals and lays down conditions for its use in medicines.

There is a separate EU regulation requiring all medicines containing bovine gelatin to be made only from bovine gelatin covered by a "Certificate of Suitability" from the European Directorate For Quality of Medicines (EDQM) confirming compliance with Ph. Eu. IIIrd Ed., no 1483, 2000. EDQM has advised that no EDQM certificate is required for porcine gelatin products.

Capsules For Animal Feeds including Nutritional Products

Regulation (EC) No 1292/2005

This regulation permits the feeding to all farmed animals of gelatin derived from non-ruminant gelatin i.e. porcine gelatin. Annex, II, point a, refers to "the feeding to farmed animals " and Annex II, point a, sub-point iii, refers to "gelatin derived from non-ruminants". This regulation expands further on the derogation for gelatin derived from skins in EU Regulation 999/2001 to all types (skins and bones) of non-ruminant gelatin.

Additional support for the feeding of porcine gelatin to food producing animals (including "ruminants") can be found in the following EU Regulations.

Regulation (EC) No 1234/2003

This regulation permits the feeding to ruminants of proteins and products derived from such proteins, including gelatin from non-ruminants (pigs), if they have been processed where applicable in accordance with Regulation 1774/2002, Article 19.

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Regulation (EC) No 1774/2002

This regulation states that Article 19 is applicable only to "processed animal proteins" and in Annex 1, definition 42 it excludes gelatin.

Annex VII, Chapter 6 of this regulation covers gelatin and lays down processing standards and requirements for importation. The porcine gelatin capsules we supply are manufactured in full compliance with this regulation and certified in compliance with Article 29(6) of this regulation.

Regulation (EC) No 999/2001

This regulation prohibits feeding of mammalian protein to ruminants in Article 7, point 1 but in Annex IV, Point 2, there is a derogation for gelatin derived from hides and skins that covers porcine skin gelatin. This derogation was further expanded on by EU Regulation 1292/2005 (see above).

EU Decision 766/2000/EC

EU Decision 766/2000 was issued on 4 December 2000 as a temporary emergency measure to prevent the spread of BSE within the EU. **This decision was repealed by 1234/2003/EC**, Article 3 issued on 10 July 2003. There continues to be confusion in the market that this regulation is in effect but it is not.

A detailed discussion of the regulations is available from Torpac on request.

We gratefully acknowledge the assistance of Dr. Uwe Seybold, Vice President for Regulatory Affairs at Gelita AG in Germany, the world's largest manufacturer of gelatin.

Please consult your regulatory advisors and local officials before you make any marketing or financial decisions based on this letter.

best regards,

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