

平成 26 年 11 月 25 日

反すう動物由来物質不使用等を確認する書面を取得するための参考様式

製造業者に「反すう動物由来物質不使用等を確認する書面」を請求する際の参考です。御自由に活用ください。ただし、書類の入手を保証するものではありません。

製造業者に反すう動物由来物質不使用等を確認する書面を要求するファックス等の例

Fax ・ Email Transmission

From _____

Phone: +81- _____

Mailing Address

Fax: +81- _____

Email: _____

Website: _____

No. of pages: including this page.

Date: _____

To: _____

Fax: _____

Phone: _____

.....
Subject: Request for TSE free certification of your product(s).

To whom it may concern,

I am (_____), (veterinarian ・ pet keeper) in Japan. I got to know this (Fax number ・ Email address) at (Internet ・ label of your product). I am going to import your product (s) listed below for (veterinary medical use ・ private use). The product(s) is regarded as pharmaceutical product(s) under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics of Japan. To import the product(s), I have to submit document, which certificates free from Transmissible Spongiform Encephalopathy (TSE), issued by manufacturer (see following papers). I would like to ask you to send me the certification. Please send me the certification by (Fax ・ Email attachment ・ letter).

Your prompt reply will be greatly appreciated.

Please (FAX ・ Email) me your reply.

Truthfully,

Name: _____

The product(s) I'm going to import:

反すう動物由来物質不使用等を確認する書面の必要性を説明する例

**Animal Products Safety Division, Food Safety and Consumer Affairs Bureau,
Ministry of Agriculture, Forest and Fisheries (MAFF), Japan**

Phone: +81-03-3502-8111

Mailing address:

Fax: +81-03-3502-8275

1-2-1 Kasumigaseki

E-mail: yakuji_kanshi@nm.maff.go.jp

Chiyoda-ku, Tokyo

Website: <http://www.maff.go.jp>

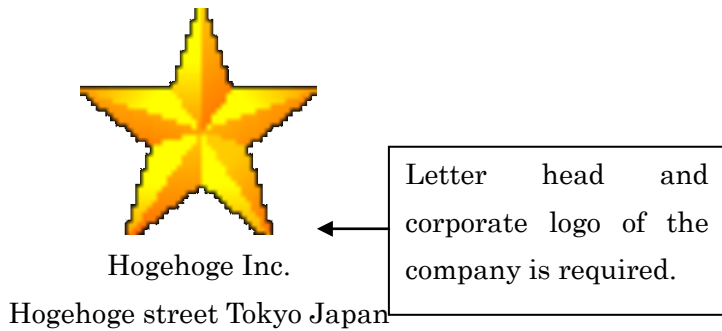
Japan 〒100-8511

To Whom It May Concern

This document is to explain what is demanded the private importer to submit for his/her import. In Japan, private importing veterinary products (including pharmaceutical products and medical devices) are permitted after documentary examination. In documentary examination, we demand importer to submit document issued by manufacturer, which certificates no ruminant materials are used in whole process of the veterinary products, for the sake of further communicable disease control of Transmissible Spongiform Encephalopathy (TSE). When ruminant materials are used, like lactose, we demand to clarify what ingredients are derived from ruminant animal used in the product, the original raw material, the species of ruminant animal and where the ruminant animal is produced in (Ex: Lactose from milk, derived from cow in Australia). In addition, please certificate no ruminant materials are used in the products except for mentioned ingredients. We would evaluate the risk of BSE according to our criteria. See following our requesting certification sample.

Very truthfully yours,

反すう動物由来物質不使用等を確認する書面の例



To whom it may concern,

TSE free certification

When ruminant materials are used, like lactose, please write its information like following example (Ex: Lactose from milk, derived from cow in Australia). In addition, please certificate no ruminant materials are used in the products except for mentioned ingredients.

We certify that no ruminant materials are used in the whole process of manufacture for the product(s) listed below.

Products:

Please clarify the products, which you certificate.

Hogehoge CancerCure

Hogehoge Surgical Instruments Tools

Hogehoge AbscessCure

• Hogehoge Scissors

Hogehoge MycosisCureShampoo

• Hogehoge Forceps

Hogehoge DiarrheaStopper

• Hogehoge Special Needles

Manufacturer: Hogehoge Inc., Japan

The name and country of manufacturer is required.

Date: DD/MM/YY

(Signature)

(Print Name)

Quality Control Manager

(Position)

Hand written signature, day signed and signer's position are required.

(Remarks)

1. When certifying all products without specifying product lot numbers, the document should have been issued no more than about one month before the date of import.
2. When certifying specific product lot numbers, it must also be confirmed that the veterinary drugs, etc., that are to be imported correspond to those numbers.