ANNEX 2

DRAFT LETTER TO PRODUCT LICENCE HOLDERS

CONCERN ABOUT BSE IN HUMAN MEDICINES

Bovine Spongiform Encephalopathy (BSE) is a disease of cattle characterised by degenerative neurological changes culminating in the death of the animal.

Although there is no evidence to suggest that BSE may be transmitted to man, the Licensing Authority considers it prudent, having taken expert advice, including that of CSM and VPC, to advise that all manufacturers whose products contain bovine material should conform to a set of guidelines. A copy of these is attached to this letter.

BSE was made a notifiable disease in 1988 (under the Animal Health Act 1981). It is therefore important that the Licencing Authority has completely up to date information on the use of animal tissues in the manufacture of medicinal products.

Accordingly I am writing to request information about all products which animal material has been used : a) as an active constituent
b) as an excipient
c) during processing or manufacture

The information required is:

- Company Name
- PL/CTC/CTX Number and Product Name
- Animal ingredient (eg tissue, blood etc)
- Animal species (eg bovine)
- Purpose of inclusion (eg active, excipient, in-process use)
- Country of origin of collected material
- Does this product conform to the guidelines at present?
- If not, over what timescale do you intend to apply the guidelines to this product?
- What are your stocks of this product at present?
- What is the anticipated utilisation of this product?

Information on each medicinal product must be submitted on a separate A4 form as attached.

This information should be addressed, for human medicines, to : The Information Room at Market Towers, by 1st May 1989. Any professional enquiries should be made to Dr Rotblat (medical) Ext.3216, and Dr Purves (pharmaceutical) Ext.3219.

Yours faithfully,

D.Hagger

PROPOSED JOINT CSM/VPC GUIDELINES FOR INDUSTRY

The following guidelines are addressed to product licence holders and applicants.

1. Scope
It is intended that all products licensed under the Medicines Act 1968 for human or veterinary use, that are administered parenterally or to the eye or to open wounds, should conform to these guidelines if they contain material from a bovine source, or if bovine material has been used during their manufacture.

Although these guidelines relate to BSE and materials of bovine origin, they should also be considered as applicable to material from sheep, goats, deer, and some other animals susceptible to scrapie-like agents.

2. Cattle source
Bovine material should come from cattle, taken from a closed herd in the female line since 1980, in which no animal has been clinically suspected of having BSE, and which has not been fed rations containing ruminant derived protein during that period.

3. Tissues excluded
No brain or neural tissue, spleen, thymus and other lymphoid tissue, placental tissue or cell cultures of bovine origin should be used in the manufacture of medicinal products.

4. Collection techniques
All possible measures should be taken to avoid contamination of the bovine material with BSE agent, in particular:

no tissue is to be used in medicinal products when collected postmortem from a bovine animal after brain penetrative stunning.

all tissue collected from the bovine animal should be taken aseptically using sterile equipment. Needles, syringes, scalpel blades etc should be disposable items.

it is recommended that whenever possible, source animals should be calves up to 6 months old.

for serum: all cellular components must be removed.

for foetal calf serum: great care should be taken to avoid contamination by placenta and foetal fluids. All cellular components must be removed.

5. Sterilisation
When sterilization procedures are used, they should be demonstrated to be capable of inactivating scrapie-like agents - at present thought to be autoclaving using a porous load cycle at 134°C-138°C for 18 minutes at 30 psi.

6. Product
Whenever possible, the product should be terminally sterilised by a validated method.

REPLY FORM FOR COMPANIES REPORTING ON ANIMAL MATERIALS

Company Name	
PL/CTC/CTX Number and Product Name	

	If more than one animal ingredient 1	2	3
Animal ingredient (eg tissue, blood etc)			
Animal species (eg bovine)			
Purpose of inclusion (eg active, excipient, in-process use)			
Country of origin of collected materiael			

Does this medicinal product conform to the guidelines at present?	
If not, over what time-scale do you intend to apply the guidelines to this product?	
What are your stocks of this product at present?	
What is the anticipated utilisation of this product?	

89/2.22/8.3