

THE DIRECTOR

RZ/PH/2011-07022L
JSH/jb

Strasbourg, 17/11/2011

Subject: Invitation to participate in the establishment of somatostatin CRS batch 6 with a new, more selective method

To whom it may concern,

The EDQM is grateful to all those who have participated in the Ph. Eur. collaborative studies and has taken note of comments from some manufacturers on the assigned content of somatostatin CRS batch 5.

Somatostatin CRS 5 has been established based on a thorough analytical investigation of its purity elicited by indications from different users. The analytical investigation was made using the compendial methods, as well as several orthogonal techniques including *inter alia* qNMR, elemental analysis, analysis of inorganics and amino-acid analysis. The body of scientific data obtained supports the currently assigned value.

However, in view of the comments received, a new batch of somatostatin CRS is to be established with a new candidate batch and a new method with improved selectivity. Subject to European Pharmacopoeia Commission endorsement, the EDQM is proposing to proceed directly to the revision of the monograph upon completion of the establishment study, exceptionally without an enquiry in Pharmeuropa.

The EDQM invites all concerned manufacturers to participate in the establishment of the somatostatin CRS 6 with the new method. Expressions of interest to contribute are welcome by 8 December 2011 by sending an email to andrea.lodi@edqm.eu.

Yours sincerely,

Dr Susanne KEITEL
Director