

From: Lockley Hannah  
Sent: Monday, February 20, 2006 7:48 AM  
To: NIEHS NICEATM  
Subject: Nomination for work Workshop participant

Dear Dr William Stokes,

We received an e-mail on Friday 3rd February, inviting the APC to nominate participants for a possible workshop on alternative methods to refine, reduce and replace the mouse LD50 assay for Botulinum Toxin potency testing.

By way of background, the APC (Animal Procedures Committee) is an advisory, Non-Departmental Public Body established and appointed under the terms of sections 19 and 20 of the Animals (Scientific Procedures) Act 1986. Its role is to advise the Home Secretary on matters concerned with the Act and his functions under it, relating to any experimental or other scientific procedures applied to a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm; and also, to examine other related subjects we consider worthy of further study. There are currently 21 members of the committee. Further information about the APC can be found at our website <http://www.apc.gov.uk>

At a recent committee meeting, the secretariat informed members of your request and the committee agreed to endorse the nomination of Dr Sesardic. Dr Sesardic is a researcher who has previously received funding from the Home Office for research into this area. Her work included progressing development of an in vitro test -

"Synthetic and recombinant technology was used to prepare the natural substrate for the botulinum type A toxin. This was used to develop an endopeptidase assay, more sensitive than the mouse bioassay, for the detection of toxin in therapeutic preparations. This has the potential ultimately to replace entirely the in vivo bioassay systems"

Dr Sesardic has recently been invited to a meeting in Strasbourg (5 April 2006) as a potential study leader of an initiative to review botulinum toxin assay methods and review the need for validation studies. Dr Sesardic is happy to be nominated as a possible workshop participant for your initiative.

Finally, in discussing this nomination at the last meeting, the committee emphasised that they view the possible workshop to be appropriate and that a high priority should be placed on progressing alternative methods to replace the mouse LD50 assay for Botulinum Toxin potency testing.

Please contact me if you require any further information.

Kind regards,

Hannah Lockley  
Deputy Secretary  
Animal Procedures Committee Secretariat