DEPARTMENT OF HEALTH AND SOCIAL SECURITY
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883669

Your reference
Our reference

Mr Jacques Ponteyne
President
Travenol-Genentech Diagnostics
600 Memorial Drive
Cambirdge, Massachusetts 02139

22 January 1985

Dear Mr Ponteyne

The Department proposes to set up an evaluation programme for investigating the performance of screening test systems for AIDS markers. Results from the evaluation programme will be used by the Department as the basis for issuing firm advice to the National Health Service on which materials may be used by them. It is anticipated that the Health Service will also be advised not to use materials which have not been tested in the programme.

The evaluation will involve a systematic study of each candidate material's performance against a panel of patient samples, both positive and negative. It will also include an investigation of factors such as the controls provided and the convenience and time required to carry out each test. Information from the manufacturer to substantiate claims made for the product's performance will also be required. The Department will base the advice that is issued on both the results of the evaluation and the information provided by the manufacturer.

This letter is being sent to all companies who are believed to be planning to sell a screening system for AIDS into the United Kingdom. The purpose is to advise companies of the Department's policy in this matter.

We also wish to ensure that undue delay is avoided between products becoming available and advice on their use being issued. If your company intends to sell such a diagnostic material into the UK, could you please assist us therefore with the following information.

1. The date when the product is expected to be available in the UK on either a trial or commercial basis and some indication of its likely cost.

2. The test method employed (eg RIA, EIA) and any special equipment that would be required for carrying out the test.

3. The nature of any controls included as part of the test system. In the case of positive controls, evidence will be required to demonstrate that it is safe to use and that HTLV III has been inactivated effectively.

4. The names of any units in the UK that you have already approached, or that you intend to approach, to carry out trials of your material.

All information provided to the Department will be treated strictly as 'Commercial in Confidence'.

Yours sincerely

GRO-C

pp R W B ALLEN
SCIENTIFIC AND TECHNICAL BRANCH