

Our Ref: DRW/GC/SL

4th December 1979

Mr. C. Jones,
Cutter Laboratories U.K.,
20 Guildown Road,
Guildford,
Surrey,
GU2 5EN.

Dear Carroll,

The precise situation with the "suspect" batches of Koāte is as follows:-

	<u>Batch No.</u>	<u>Assigned Potency</u>	<u>Quantity Received</u>	<u>Current Stock</u>	<u>Material Sold</u>
1.	C 1090	1100	550,000	546,700	Nil
2.	NC 8160	230	920,000	290,490	628,590
3.	NC 8185	230	496,800	370,530	125,350
4.	NC 8184	1130	565,000	559,350	Nil

As you will realise from the quantity involved, we have a major problem. On the one hand, we are desperately short of "good" stock and, clearly, we dare not sell new batches without first obtaining NIBS clearance. So your urgent help with prompt despatches is of paramount importance. The other side of the coin is that we have two major and influential customers, Oxford and Newcastle, reluctant to trust our assay figures and insisting on their own check prior to acceptance.

More detailed comments on the individual batches are:-

1. C 1090

Not acceptable to NIBS unless we re-label at 900. My own view is that this should be returned to the U.S.A.

/contd.....

Mr. C. Jones

4th December 1979

/contd....

2. NC 8160

This lot has been extensively used in Oxford and Newcastle and is the subject of the attached letter from Rizza and Jones.

NIBS obtained 210 and cleared at 230. Repeat assays at Oxford indicate 185.

For the present, I have supplied replacement material free of charge to both centres. Probably the simple way out financially, is to give them units equivalent to their "loss", say 20%, or 126,000 units. Obviously we will be looking to Cutter for compensation.

The balance of this lot is frozen and should be returned to the States.

3. NC 8185

This was cleared by NIBS at label declaration, although their assay was around 10% low. There is no concrete evidence that anything is wrong with it as yet, but neither Oxford nor Newcastle will take this lot because of a suspicion of 230 material generally.

I suggest we leave this on one side until the dust has settled.

4. NC 8184

NIBS again got 900 and will not clear without re-label. I originally stated that we would sell to France at label strength and in fact, we have sold them 200,010 units. However, in view of total problem, I feel it is not sensible to continue this policy.

On balance, I now believe this should be replaced by Cutter.

Of course, any recommendations on these batches could change if your technical people can resolve the matter with NIBS. I do hope you can achieve an agreement quickly.

So far as the Cutter/Speywood financial aspects are concerned, I hope your accounts people will hold any action on invoices covering these lots until we can get some sense into the situation. Vernetta has already chased me regarding NC 8184 and I have replied that the lot is in quarantine and we therefore cannot pay.

/contd.....

Mr. C. Jones

4th December 1979

/contd.....

Please do all you can to keep this matter moving.

Yours sincerely,

David R. Williams
Director