Cutter

file

TO: Those copied below

DATE: September 9, 1982

COPIES TO:

FROM: L.G. Hershberger

SUBJECT: Meetings at FDA and PMA, week of 8/30/82

T.H. Heinrichs/W.F. Schaeffler/J.V. Hjorth/T.J. Leverte
M.M. Sternberg/R.J. Guzman
J. Olshansky/R. Devore
~~M.J. Welch~~/J. Cherry/P. Short/L. Franke/J. Huxsoll/~~T.L. Brown~~
R.H. Rousell/J.A. Canham
M. Mozen/D.D. Schroeder
J. Hink/K.H. Fischer/C.K. Turner
J. Ryan/J. Barnette/Jan Peterson
J.N. Ashworth
L. Ambrus
D.E. Soules
E. Weichert/M. Monroe - CLAYTON
M.W. Giboney - SPOKANE
B. Morris - CLAYTON
G.M. Nakamura/E.A. Cutter/B. Bradley
R.L. Cole
~~T.E. Dwyer~~

DEPOSITION EXHIBIT 51 9-22-95 C. Moore

GENERAL-PURPOSE IV SOLUTIONS

Copies of the August 26, 1982 press release on discontinuing the production of these products were discussed with key people at the Office of New Drug Evaluation and Office of Biologics.

If we do not wish to maintain NDAs on discontinued products as valuable assets we should send a letter to each NDA file stating that:

1. We request withdrawal of the NDA without prejudice because we are no longer interested in marketing the product.

2. We waive the right to a hearing

3. We are not abandoning the NDA and wish to maintain confidentiality of information in sections X through Z.

Related INDs should also be "discontinued" to preserve confidentiality.

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Plaintiff's Exh. #0225

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ISG STABILITY

Don Tankersley was completing a three-year study on each manufacturer's product designed to correlate initial enzyme levels with stability parameters. He is obtaining a statistically significant correlation although the correlation is not as good as he would like. Some Cutter lots do not look very good. He plans to present some of the data at the September 23 workshop on molecular integrity. His personal opinion is that three-year dating is too long for some manufacturer's products.

Acquired Immune Deficiency Syndrome

Dr. Donohue had called all manufacturers of AHF the week before and requested that they voluntarily refrain from fractionating plasma into coagulation products if the plasma came from centers known to have a high population of homosexuals.

I told him that I had discussed this with our production and technical people and we had placed a hold on this for one month. (Actually we will not be fractionating any of this material into factors VIII and IX for sale anyway). I also told him I expected to obtain confirmation from management (SBU) to continue the hold beyond the one-month period. Donohue feels that the hold will not be necessary for more than two or three months unless more donors develop AIDS.

The request for voluntary compliance was briefly discussed with Mike Rodell of Hyland and he expressed great surprise that we would even consider fractionating this material into factors VIII and IX (anything other than HBIG) because of the history of hepatitis problem.

It would certainly appear to me that plasma from these sources will be suspect for political reasons for some time. We should move ahead rapidly with our program for hyperimmunizing donors with Merck vaccine to provide source material for HBIG.

The National Hemophilia Foundation has agreed to monitor their members closely for AIDS and has requested $10,000 from the manufacturer's of AHF ($2500 from Cutter) to support this study. I asked Mike Rodell if Hyland thought we should support this and he said "No, but we have to!"

BACTERIAL ENDOTOXIN TEST

The MVD (maximal valid dilution) concept proposed by Terry Munson of FDA has not been accepted by the USP yet. This appears to be an indirect way of trying to set limits for sensitivity and is being opposed by PMA.

MONOCLONAL ANTIBODIES

Dr. Parkman of FDA is requesting input from manufacturers on proposed regulatory guidelines/regulations. This will be provided by the diagnostic subcommittee of the PMA Blood and Blood Products Division.

CONTAINER-CLOSURE INTEGRITY TESTS

Some firms use and want to continue to use the sterility-stability test. The PMA Guideline draft is being revised to allow this. The revised draft will allow a broad list of approaches with nothing on "how to".

There was strong sentiment for not publishing anything by PMA, but I pointed out that the FDA was forcing LVP manufacturers to use the stability-sterility test or an acceptable alternative to obtain NDA approvals and that our QA Division was strongly opposed to the sterility-stability test. Their answer to that was, "Then Cutter should use an alternative test". I personally feel that it would be worthwhile to develop a PMA document that contains the concept of container-closure integrity for a system so the work does not have to be repeated on each product using the same container-closure system whether we use sterility or an alternative test. Nothing will be completed until the joint committee from the PMA QC and Biological Sections get together again.

LOGMARS BAR CODING ON LABELING FOR MILITARY CONTRACTS

There will be no backing off from this requirement. They will, however, be somewhat reasonable about the time of implementation and for now they will only require the bar coding on the shipping case and each intermediate carton. Eventually they will want it on every unit of issue unless there is absolutely no room on the label.

All companies represented planned to go outside to obtain the bar coding initially and about half were making plans to develop their own in-house capability for future use.

A letter from PMA to DOD/DPSC/DLA was drafted stating that:

1. The industry will have the capability to comply during the first quarter of 1983. (Actually most companies were going to start by October 1, 1982).

2. Position of bar code to meet 1/8" tolerance in specs will be a serious problem. The PEMM Section of PMA will be asked to evaluate the spec to determine what is reasonable. (The military wants these close tolerances for automated warehousing).

3. PMA estimates that the total cost of the LOGMARS will be in the range of $ .50-$1.50 per application rather than the .03 or .04 estimated by the military.

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