

LAW OFFICES

KLEINFELD, KAPLAN AND BECKER

1140 NINETEENTH STREET, N.W.

WASHINGTON, D. C. 20036-6606

TELEPHONE (202) 223-5120

FACSIMILE (202) 223-5619

E-MAIL: kkb@kkblaw.com

THOMAS O. HENTELEFF
RICHARD S. MOREY
PETER O. SAFIR
KINSEY S. REAGAN
PETER R. MATHERS
BONNIE A. BEAVERS
DANIEL R. DWYER
GLENN E. DAVIS
PRESCOTT M. LASSMAN
STACY L. EHRLICH
JENNIFER A. DAVIDSON
STACEY L. VALERIO
ROBERT O. WINTERS

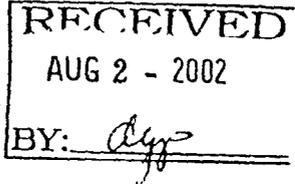
WEST COAST OFFICE:
ONE MARKET STREET
STUART TOWER, SUITE 1450
SAN FRANCISCO, CA 94105-1313
TELEPHONE (415) 538-0014
FACSIMILE (415) 538-0016

VINCENT A. KLEINFELD
1907-1993

ALAN H. KAPLAN
1930-2001

OF COUNSEL:
HARVEY A. SUSSMAN

July 26, 2002



Charles Ganley, M.D., Director
Division of OTC Drug Products, HFD-560
Center for Drug Evaluation and Research
Document Control Room, Room S212
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

Dear Dr. Ganley:

We note that the OTC Division recently sent a letter (June 5, 2002) to Becton Dickinson informing them that their Bactec kit product must bear "Drug Facts" labeling on the outer package. This letter was excerpted in The Tan Sheet of June 24, 2002, page 11. We do not represent Becton Dickinson in this matter. We are commenting on this correspondence on behalf of another client.

The Bactec product is apparently intended for sale to healthcare professionals only, not to consumers. In Becton Dickinson's request to the FDA that firm stated its conclusion that this product should be exempt from the Drug Facts rule, 21CFR 201.66, because the convenience kit was intended solely for distribution to healthcare professionals and for use in healthcare settings.

In our opinion, Becton Dickinson is not alone in coming to this conclusion. We understand that other professional kits and individual products intended for professional use are labeled or could be labeled in such a way that the agency would consider them similar to the Bactec product with respect to the need for Drug Facts labeling. Accordingly, it would be most helpful to manufacturers of OTC products intended solely for distribution to healthcare professionals in hospitals, clinics, and other sites used by

98N-0337

Let 14

KLEINFELD, KAPLAN AND BECKER

Charles Ganley, M.D., Director
Friday, July 26, 2002
Page 2

providers of health care if the agency would issue an official statement addressing this matter more fully.

Specifically, we suggest that it would be useful for the agency to issue an official statement as to its position on the addition of text which would qualify products intended for professional use only to be exempt from some or all of the label format requirements required by 21 CFR 201.66(d). These qualifying statements could include the following types of text to be prominently featured on the principal display panel of all affected packaging:

"For Hospital/Professional Use Only", "Not For Retail Sale", or "Not Labeled for Consumer Use".

We request that the agency issue a guidance or equivalent document as an aid to manufacturers who have considered their professional use only products to be exempt from the need to label outer containers in the Drug Facts format, and wish to continue in that status.

Yours very truly,



Richard S. Morey