

Printed by Leanne Cusumano  
**Electronic Mail Message**

**Sensitivity:** COMPANY CONFIDENTIAL

**Date:** 15-Aug-2000 05:09pm  
**From:** Leanne Cusumano  
CUSUMANOL  
**Dept:** HFD-007 WOC2 3040A  
**Tel No:** 301-594-5627 FAX 301-827-5562

**O:** See Below

**Subject:** Memorandum of Telecon with Tess Castle, Advamed & Lisa Skeens, Baxter

Dr. Chiu and I spoke with Tess Castle of Advamed and Lisa Skeens of Baxter this afternoon to convey the decisions made at yesterday afternoon's meeting. We stated:

1. We do plan to issue a proposed rule proposing an implementation date of 01/26/2003 and to permit SVPs to state they contain less than 25 ug/L instead of an exact amount.

Ms. Skeens asked if this was an across the board exemption, and we confirmed that it was.

2. We stated that we are not planning any exemptions for particular products, and that this should be workable in light of the extended implementation date.

3. We stated that we are not planning to permit any PBP to be labeled on the package insert rather than the immediate container because of the public health concern associated with not knowing whether any particular PBP would be used for SVPs or LVPs.

Ms. Baxter stated that industry should be able to label the immediate containers by the extended implementation date.

Ms. Baxter then asked whether FDA planned to issue a guidance document, given the amount of time it can take to issue a proposed rule. We informed her that we would issue a guidance if the rule was not completed before the current implementation date of January 26, 2001.

We asked if there were any outstanding issues that we had not addressed, and Advamed & Baxter stated no.

LC

**Distribution:**

<b>TO:</b> David Read	( READD )
<b>TO:</b> Virginia Beakes	( BEAKESV )
<b>TO:</b> David Lewis	( LEWISD )
<b>TO:</b> Yuan-Yuan Chiu	( CHIU )
<b>TO:</b> Eric Colman	( COLMANE )
<b>TO:</b> Eric Sheinin	( SHEININ )
<b>TO:</b> ERICA L KEYS (OC)	( EKEYS@OC.FDA.GOV )
<b>CC:</b> Duu Gong Wu	( WUD )
<b>CC:</b> Nancy Sager	( SAGERN )
<b>CC:</b> Charles Hoiberg	( HOIBERG )

MT,

9nn-0056