

A18502

TO	FIELD POINT OR DEPT. & BLDG. NO.	DATE YOUR LETTER
B. Hendrix, D. Kickel		
FROM	FIELD POINT OR DEPT. & BLDG. NO.	DATE THIS LETTER
Daphne Benderly		11/16/90
SUBJECT		

→ WCB

FDA RED DYE # 3 PIGMENT

As of August 25, 1990, the FDA removed red dye #3 from its list of acceptable ingredients (see note from Chuck Purks). This was known to the R & D groups and the Industry Support groups since March 1990 (see attached memos). A list of compounds was compiled to see what had to be rematched. The customers affected are those that require FDA acceptability for their product, either for their own requirements, or the requirements of their customer. In most cases, only a color re-match would be required, along with customer approval.

The most difficulty in changing formulation is in the case of the products promoted as both FDA acceptable and USP certified (86310 series, 86153 series). The compounds as currently formulated are not FDA acceptable. A change in the toner system (i.e. a change in formulation) to make the compounds FDA acceptable would mean that the USP certification is no longer valid. The choice is therefore to have two different colors of a compound, one FDA and the other USP, or to rematch the color and resubmit for USP. The first choice would involve a great deal of customer and sales force confusion, and the second choice would involve large expenses.

At this point, no formulation changes have been made, and our product literature is incorrect. The brochure states that our compounds meet both FDA acceptability and USP approval.

I gave a training talk on BFG medical grade compounds to General Polymers salesmen, and informed them about the discrepancy in the literature. I was surprised to find that the BFG sales force had not yet been informed of the change, and the literature has not been modified.

I am concerned because we are currently selling, recommending, and promoting materials that do not meet the performance stated in our literature. This performance is required and/or desired by our customers. This is especially disturbing since these compounds are targeted for the medical market, which has very strict requirements and the possibility for high liabilities.

In September, CIM Business Management suggested the following actions:

- 1) Determine which compounds containing this pigment are marketed as FDA acceptable.
- 2) Obsolete FDA compounds that are no longer being sold.
- 3) Contact the customers, and determine whether the product requirement is FDA or USP. If it is FDA, inform the customer of the change.

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- 4) For FDA only required applications, rematch the color.
- 5) For USP only required applications, no action is needed.
- 6) If both USP and FDA are required, either USP re-certification is needed, or the compound can no longer be sold.

Items 1 and 2 were completed by R & D. Some compounds have been rematched, but I am not sure if the new compounds have been sold to customers. The 86310 was submitted for a color match, and the first attempt was not close enough. I do not think that a color match request has been entered to rematch the 86310 to a more acceptable color. To the best of my knowledge, no customers have been notified of the change.

cc: Jim Daly
Ken Srail
Henry Forsyth
Bud Pazur
Sally Mathers
Chuck Daniels
Marty Zemanek
John Dresch
Charlie Ragland
Jim Gray
Lance Mitchell
Cheryl Brubaker
Dana Mitchell
D'Lane Wisner
Elizabeth McKay
Kala Spangler
Mike Miller
Mark Hross
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Bob Hinderer
Bob Cambell
Dick Tannehill
Jim Velordi
Dale Kramer
Joe Powell