DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Drive, Suite 500 Nashville, TN 37217 (615) 366-7801	12/3-4&7-11/09
	FEI NUMBER 3002147105

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Paul G. Reiland, Supply Chain Mgr.

FIRM NAME	STREET ADDRESS
Unilever Covington	2000 Hwy 51N
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Covington, TN 38019-2009	LACF Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

1) Entries on aseptic system processing records were not made at the time the specific processing system operation occurred. Specifically, a manual entry on the Aseptic Processing Log for (b) (4) line (b) (4) at 10:42 on 9-23-09 states that the system was operating on water (OW) although other processing records (UHT and Homogenizer recorder charts and the (b) (4) temperature strip chart) indicate that the switch (from product) to operating on water (OW) did not occur until 9 minutes later at 9:51.

2) Process deviations were not recorded in a separate file or log that details both the deviation and the actions taken. Specifically, process deviations are listed in a (b) (4) (b) (4) These categories include both quality deviations and process deviations.

3) Investigations of elevated (b) (4) kick out/reject rates and Spoilage Reports have not been adequately described and documented, and no HOLD log is available to track and verify investigations of such incidents. Specifically, as indicated by the following:

- for production lot (b) (4) the Spoilage Report is hand identified "Not Released" and undated, unidentified lists of at least (b) (4) cans (with hand written apparent processing times) were found with the (b) (4) reject reports and Spoilage Reports, with no explanation of what these documents represent or what investigation was conducted, other than the hand written notation on the front page of the can list records, which states "NOTHING FOUND".

- for production lot (b) (4) the Spoilage Reports dated 11/18-19/09 indicate that at least (b) (4) cans were identified as "swells/sour", and (b) (4) cans were identified as (b) (4) failures, with no documentation of any follow-up investigation to date.

- for production lot (b) (4) the Spoilage Report indicated (b) (4) sours were detected and an investigation was conducted 9/1/09, but no documentation is available to show that the recommended preventive actions were satisfactorily completed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Cheryl G. Scott David R. Heiar	**Cheryl G. Scott / Andrew F. Saunders / David R. Heiar / Lindsay M. Hughes / Marcus L. Head**	**12/11/09**