



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

November 28, 2006

Ferrolabs, Inc.
21525 Ridgetop Circle, Suite 260
Dulles, VA 20166

Re: Prenotification Consultation (PNC) 542

Dear Dawn:

This is in response to your letter of September 18, 2006. In the letter, you requested FDA's concurrence for one of your lubricants/seals, Ferrofluid-FLS 040.040, as a lubricant/seal in a top-mount mixer for bioreactors/fermentors, which will be used in food industry. Your inquiry has been recorded in our files as Prenotification Consultation (PNC) 542. In your letter, you also mentioned that Ferrofluid-FLS 040.040 will not be intended to contact with the microorganisms and products produced in bioreactors/fermentors. Therefore, you believe that the use of Ferrofluid-FLS 040.040 in top-mount mixer applications constitutes a non-food additive situation. Furthermore, you indicated that, except for polydiethylsiloxane, all the chemicals used in the manufacturing process are either regulated as lubricants (21 CFR 173.210 for acetone and 21 CFR 173.270 for hexane) or listed as generally recognized as safe (i.e., aqua ammonia, ferrous sulfate heptahydrate, ferric chloride hexahydrate, acetic acid, and stearic acid).

We have reviewed the information provided in your letter and concur that the intended use of your product is not a food additive situation as defined in Section 201(s) of the FD&C Act. In this section, the term "food additive" means "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use)". The proposed intended use of your product, as a lubricant/seal in top-mount mixers for food industry's bioreactors/fermentors, would clearly not meet the definition of a food additive. As such, the intended use of Ferrofluid-FLS 040.040 would not require FDA's pre-market review under the food additive petition or the food contact substance notification process.

If you have further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

A handwritten signature in blue ink, appearing to read "Anita Chang".

Anita Chang, Ph.D.
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition