Appendix F: NIOSH IRB Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date March 12, 2013

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH IRB (HSRB) – Protocol No. HSRB 13-DRDS-01 "Spectrum of Flavoring Chemical-Related Lung Disease, Part II" Approval of Protocol

To Rachel Bailey, D.O., M.P.H.
Project Officer, DRDS
Through: /Chief, FSB, DRDS ____ ____
/Director, DRDS ____ ____

The subject protocol was reviewed at the 2/12/2013 and 3/12/2013 convened meetings of the NIOSH IRB (HSRB) and granted deferred approval. We received your response (E-mail dated 3/29/2013, and hard copy received 3/31/2013) and find it is responsive to my 3/12/2013 E-mail report. The revised protocol and consent documents (dated 3/12/2013) are **approved** for one year and will serve as the documents of record for this study **(renewal date 3/12/2014)**. However, if you make any substantive changes, or any adverse reactions occur in any study participants, please notify me immediately. Protocol incidents need to be reported to NIOSH IRB by phone or E-mail within 2 working days; and reported formally [send CDC form 0.1254 + 0.1379] within 2 weeks.

If you choose to make changes to your approved protocol, the changes must be reviewed and approved prior to implementation by submitting via hard copy CDC forms 0.1379 (signature page), 0.1252 (amendment request), 0.1370 (non CDC collaborator, if have), a clean copy of the revised protocol and a highlighted copy (track changes or pen/ink) of the revised protocol (all changes highlighted). Electronic submission of your amendment request may facilitate review, but it is not required. The general procedure for requesting annual continuing review is to send 45-60 days prior to renewal date completed hard copy forms CDC 0.1379 (signature page), 0.1251 (continuing review request), 0.1370 (non CDC collaborator, if have), a copy of your current consent form (if consenting or recruiting currently). An electronic submission of your continuing review may facilitate review, but it is not required.

Protocol Issues, Consent Form Issues, Addenda Issues – None.

End of report

for Kathy Mastorson
Mark A. Toraason, Ph.D.

cc:
HSRB 13-DRDS-01