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COMMENTS ON:

NTP TECHNICAL REPORT ON THE TOXICOLOGY STUDIES OF GREEN TEA EXTRACT IN F344/NTac RATS AND B6C3F1/N MICE AND TOXICOLOGY AND CARCINOGENESIS STUDIES OF GREEN TEA EXTRACT IN WISTAR HAN[Crl:WI(Han)] RATS AND B6C3F1/N MICE (GAVAGE STUDIES)

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SHORT TITLE:

COMMENTS ON THE NTP TECHNICAL REPORT OF THE TOXICOLOGY AND CARCINOGENESIS OF GREEN TEA EXTRACT

These questions are being asked for the Review Committee to clarify when transferring this DRAFT to final form to facilitate this Technical Report being better understood and applicable:

1. GREEN TEA EXTRACT

How was the green tea extract prepared by the supplier? Aqueous? Tincture involving hydrocarbons starting with ethyl alcohol? What baseline screening did the supplier perform on the tea leaves for pesticides, heavy metals and organics before the extract was performed? Please list any and all solvents, detergents, inorganic or organic chemicals that the supplier used in extract preparation and final formulation?

2. CONTAINERS, SHIPPING AND STORAGE CONDITIONS

Please describe the containers and extremes of temperature of the green tea extract during shipping and during the time period the green tea extract was kept in the laboratory? Was BPA or were there phthalates in the contiguous containers or measuring devices?

3. GAVAGE ADMINISTRATION

How was the gavage solution prepared for administration? Was food and/or water withheld during gavage; and, if so, how long? Was the feeding *ad libitem* ? Was water *ad libitem* or restricted? Were BPA or phthalates in the gavage administration equipment? Was emesis or fecal discharge associated with gavage and was that recorded?

4. DOSAGE IN HUMANS

What are human doses of green tea extract; and, how do these convert to mg/kg doses of green tea extract advised on the labels of commercially available green tea extract preparations. What are the human blood levels of catechins on these doses? ? Is there a recommended length of time for administration advised on human green tea extract labeling, or is there no time limit? This is pertinent in view of liver damage

5. HOW IS GREEN TEA EXTRACT FEDERALLY CLASSIFIED?

Imported teas are inspected in the New York District Office of the FDA, separately from foods and drugs. Is green tea extract considered differently regulated compared to foods, drugs or dietary supplements by the FDA? This is pertinent because this is a NTP report and the FDA is an agency in the interagency signatory honoring NTP studies.

Again, these questions are asked for clarification; and, to provide better understanding and applicability to this important NTP Report.

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Disclosure: Dr. Kurt discloses formerly serving a NIEHS fellowship at Harvard (Public Health), and serves as a SGE (Special Government Employee) for the FDA advisory committee process (no reviews involving green tea).

Disclaimer: These comments reflect Dr. Kurt's personal opinions and do not do not reflect his affiliations with any academic institutions or professional societies.