

April 2, 1984

If use of aspartame is approved in drugs, Turner said, that, too, will be objected to, and a hearing will be sought on that issue as well.

FDA could have averted all this activity by granting a hearing last fall, Turner pointed out, commenting that he believes the agency's Bureau of Foods is adamantly opposed to a hearing, while the General Counsel's office is more inclined to grant one.

The Washington attorney attributed the Bureau's "adamant" opposition to a hearing to the fact that it could place Bureau personnel in an "embarrassing situation," alleging that some senior Bureau officials called aspartame's potential hazards to the attention of the consumer organizations and could be faced with having to take a different stand in public.

The Bureau could "avoid embarrassment by admitting" it made a mistake, Turner observed, commenting that he does not expect this to happen.

In his statement, Leonard charged that FDA field investigators are not always using the forms developed to collect details of aspartame complaints. He revealed that copies of the forms will be sent to those who report aspartame-related symptoms by the Aspartame Resource Center, to monitor the FDA investigations.

Included in the press package was a statement by Dr. John Olney, professor of psychiatry and neuropathology at the Washington University School of Medicine, St. Louis, holding that "Although proof is lacking (because definitive studies have not been conducted) there is ample basis for hypothesizing that aspartame is responsible for certain adverse effects reported by consumers."

Olney postulated that headaches and depression could stem from perturbations in brain levels of biogenic amines, while menstrual disorders could result from the flooding of endocrine regulatory centers by specific transmitters, convulsions from abnormal brain levels of phenylalanine, and visual blurring and dizziness from sudden decreases in blood pressure secondary to tyrosine influx into the brain.

Aspartame is an "active" substance for many people that should not be allowed in the food supply without a thorough assessment of the risk and without notice to the public of the risks, which, go "far beyond" the possible risk to phenylketonurics, Turner declared.

Once these risks are aired in a public forum, such as an FDA hearing, Turner said, it will be concluded that aspartame is not safe. He added that if this conclusion is not reached, the group will return to the courts.

GAO SEES NO PROBLEM IN DIFFERING VIEWS ON DIET IN 2 NAS REPORTS

A General Accounting Office review of why the National Academy of Sciences issued reports in 1980 and 1982 which differed substantially on whether diet changes can influence health apparently found little to dispute in the methods used by the NAS or the conclusions reached by the different scientific committees drafting the reports.

The draft GAO report, which has been circulated to government agencies for comment, reviewed the conduct and the scope of the NAS reports, "Toward Healthful Diets," which argued in 1980 that no sound scientific basis exists for recommending diet changes (See FOOD CHEMICAL NEWS, June 2, 1980, Page 3), and "Diet, Nutrition and Cancer," which suggested a half dozen interim guidelines likely to reduce the risk of cancer (See FOOD CHEMICAL NEWS, June 21, 1982, Pages 28 and 35).

NAS told the GAO investigators that it was satisfied that each group that authored the reports was competent to address the issues, was unbiased in its evaluation of the scientific data, responsible in its interpretation, and fair in its presentation of study results.

GAO concluded that the Academy's standard processes were followed by the groups which authored the two reports.

According to the NAS, the two reports are not comparable, having been written for different purposes, for different audiences, covered different topics, at different points in time, and by different groups.

Much of the diet evidence available to the authors of the second report was not available to the first group, according to the GAO draft.

It also contrasted the 1980 report, which was characterized as a 24-page position statement with a 1-1/2 page discussion and recommendation, with the 1982 report, which was a 460-page scientific literature review.

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Noting that there are two schools of thought about dietary advice, the GAO reported that legitimate disagreements will continue to exist. Nutrition science has not developed sufficiently to provide all the answers to questions about diet, according to the GAO, which also pointed out that no standard of scientific evidence has been agreed upon for making public recommendations.

GAO found some fault with the press releases which accompanied both reports, pointing out that examples of foods were mentioned in the releases, which were not mentioned in the reports.

The draft noted that this had caused agricultural interests to complain about their products being unfairly singled out.

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Few recommendations will be contained in GAO's final report on how to improve NAS reports. However, GAO will recommend that the Academy should emphasize to its study groups the importance of setting forth how they arrive at conclusions and recommendations.

Additionally, GAO will advise that NAS should also consider including a statement in future public reports that sets out scientists' disagreements about what scientific evidence is sufficient to provide public advice on topics such as diet's relationship to health.



NMFS CRAB RESEARCHER SUPPORTS GENUS LITHODES INCLUSION AS "KING CRAB"

Seven Seas has submitted supporting arguments from National Marine Fisheries Service crab researcher David A. Somerton as a supplemental filing to its petition requesting the Food and Drug Administration to recognize *Lithodes aequispina* and *Lithodes antarctica* as the scientific names for King crabmeat, requesting inclusion of those species in common or usual name regulations for "King crab" (See FOOD CHEMICAL NEWS, Feb. 20, Page 18).

Somerton said that due to recent declines in the Alaskan red and blue King crab (*Paralithodes camtschatica* and *P. platypus*), "stocks of much of the domestic production has shifted to the deeper water brown King crab (*Lithodes aequispina*). Stating that brown King crab and southern King crab are "in the same genus, from a taxonomic perspective," Somerton