July 24, 2020

Shou-Mei Wu
Director General
Taiwan Food and Drug Administration
161-2, Kunyang St, Nangang District
Taipei City 11561, Taiwan

Dear Ms. Wu,

Thank you in advance for your time. We are writing to urge the Taiwan Food and Drug Administration (TFDA) to revise the proposed draft regulation titled, "Method for Efficacy Assessment of Health Food for Joint Protection," by removing the recommendation for animal tests and prohibiting the acceptance of animal testing data.

In its proposed draft regulation, the TFDA is instructing experimenters to inject cartilage-dissolving enzymes into the joints of young rats or to sever their joint tissue surgically to induce painful osteoarthritis, feed them the health food products for 12 weeks, starve them for 12 hours, and then euthanize and dissect them. Pain relief would be intentionally withheld so as not to mask their pain and interfere with the results of the incapacitance test, a surrogate measurement of the joint pain induced by osteoarthritis. Not only does this cause severe suffering, but it also does not accurately model osteoarthritis in human populations.

The TFDA's proposed regulation also recommends and allows for human tests, and applicants can choose to conduct either human randomized controlled trials involving osteoarthritic patients or the rat tests as stand-alone evidence. This makes the experiments on rats obsolete and redundant, and TFDA should disallow the animal tests.

It is well-known that rats and humans eat different foods, have different metabolism and other important pathophysiological differences. The translation from animal tests to clinical use has been poor—despite decades of animal tests, there is no disease-modifying drug for osteoarthritis.

Regulatory bodies in the U.S., Canada, and the European Union require human test data for health claims for foods. Animal test data are not required or even suggested because they cannot provide sufficient evidence for human health claims and they could generate misleading claims.

Avoiding animal tests is a global trend in the food and beverage industry and there is a growing effort in global harmonization of various regulations. We respectfully urge you to follow suit and prohibit animal testing for this draft regulation and instead only allow for data from compassionate, human-relevant, non-animal research methods. Thank you.

Sincerely yours,

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(On behalf of Physicians Committee for Responsible Medicine which represents 175,000 members including 12,000 physician members.)

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