maximum lifetime risk of cancer in the test animals of 1 in 1 million.

S₀ means the concentration of a residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to the human consumer. For the purpose of §500.84(c)(1), FDA will assume that this S₀ will correspond to the concentration of test compound in the total diet of test animals that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million.

Sponsor means the person or organization proposing or holding an approval by FDA for the use of a sponsored compound.

Sponsored compound means any drug or food additive or color additive proposed for use, or used, in food-producing animals or in their feed.

Target animals means the production class of animals in which a sponsored compound is proposed or intended for use.

Target tissue means the edible tissue selected to monitor for residues in the target animals, including, where appropriate, milk or eggs.

Test animals means the species selected for use in the toxicity tests.

Threshold assessment means FDA’s review of data and information about a sponsored compound to determine whether chronic bioassays in test animals are necessary to resolve questions concerning the carcinogenicity of the compound.

§ 500.86 Marker residue and target tissue.

(a) For each edible tissue, the sponsor shall measure the depletion of the residue of carcinogenic concern until its concentration is at or below Sₘ.

(b) In one or more edible tissues, the sponsor shall also measure the depletion of one or more potential marker residues until the concentration of the residue of carcinogenic concern is at or below Sₘ.

(c) From these data, FDA will select a target tissue and a marker residue and designate the concentration of