time. The case of DES itself demonstrates the results of attempts by the agency to utilize procedural short-cuts. (As discussed in section I of this Decision, the previous withdrawal of approval of these NADA's was overturned on judicial review.) Thus, in the absence of a clear showing that, in accordance with the dates announced above, the implementation of this decision will seriously disrupt the meat production industry, the FDA intends to make this decision effective on these dates.

VIII. Conclusion

My conclusions with respect to the various issues in this hearing, together with citations to the record in support of my conclusions, have been stated as part of my discussion of those issues. The following is a summary of those conclusions:

1. Neither the mouse uterine/paper chromatography method, which is the currently approved method, nor any other analytical method has been shown to be acceptable to be approved or to remain approved for purposes of the so-called "DES exception" to the "Delaney Clause," 21 U.S.C. 360b(d)(1)(H).

2. DES is a carcinogen when ingested by animals. Evidence in the record suggests that DES is a carcinogen when ingested by human beings. There is no known no-effect level for the carcinogenic properties of DES.

3. Because I have revoked approval of the analytical method for detecting DES residues and have not substituted for it any other approved method, DES cannot qualify for the "DES exception" to the "Delaney Clause." The Delaney Clause, therefore, applies to DES and, because DES has been found to induce cancer in animals, requires withdrawal of approval of all DES NADA's 21 U.S.C. 360b(3)(1)(B); (d)(1)(H).

4. DES has adverse biological effects other than carcinogenesis, specifically teratogenic and mutagenic effects, which raise serious questions about its safety. On the record in this proceeding, those questions have not been resolved. No safe tolerance levels can be established for these effects.

5. The record demonstrates that use of DES animal drugs pursuant to their approved conditions of use (and, with respect to DES used in animal feed, use with a 14-day withdrawal period) results in residues of DES in the edible tissues of treated animals after slaughter. Although it is impossible to tell at what level these residues appear, residues will result at levels that must be regarded as significant from a public health standpoint. There has been no showing that any level of DES residue in edible tissues of treated animals is safe.

6. The Bureaus have provided new evidence that, together with evidence previously available, shows that the DES animal drugs are not shown to be safe for use under the conditions of use upon the basis of which the DES NADA's were approved. Approval of those NADA's must, therefore, be withdrawn pursuant to 21 U.S.C. 360b(e)(1)(B).

7. FDA is not authorized, under the Food, Drug and Cosmetic Act, in considering the question whether a new animal drug has been shown to be safe for use, to weigh the "socio-economic" benefits that that drug provides against a health risk to the ultimate human consumers of treated animals. Even were I to attempt to weigh the benefits of DES against its risks, this record would not provide sufficient information to compute the risk associated with DES or to determine whether, and to what extent, use of DES provides any health benefit or even any economic benefit to society.

8. This record provides no evidence upon the basis of which I can conclude that there are any conditions of use of the DES animal drugs under which use of those drugs would be shown to be safe. The discard of all livers (or any other organs) of these animals would not constitute a condition of use that has been shown to be safe.

9. Because alternatives to DES are available, I conclude that the withdrawal of approval of these NADAs will not significantly affect the quality of the human environment.

Dated: June 29, 1979.

Donald Kennedy,

Commissioner of Food and Drugs.

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