ing 26 out of 30 patients with edema, but fails to disclose the fact that these authors utilized concomitant adjunctive therapeutic measures in those patients where required (including bed rest, digitalis, codium restriction, etc.), and further that they reported side effects of hypokalemia, mild azotemia with weakness and postural hypotension, a tendency toward hypontremia and hypochloremic alkaloris, and salt depletion.

(4) The mailing piece, in citing the 1959 statement by Clark (Reference No. 8), fails to make clear that this statement reported observations based not on an acceptable clinical study, but on only two patients with edema whom he treated with Esidrix in the course of his practice. Further, the mailing piece cites the Clark statement to support efficacy in diuresis of "steroid-induced edema", while the Clark statement discloses that he did not know whether the edema was caused by the disease itself or the steroid therapy.

2. The advertisement in the September 21, 1964 edition of the Journal of the American Medical Association failed to present a brief summary relating to side effects, contraindications and effectiveness of the drug Esidrix, as follows:

(a) The advertisement omits the essential information set out above at Count I, § 2(a)(1).

(b) The advertisement did not present a fair balance of information on effectiveness and side effects and contraindications in that the advertisement distorts scientific reports, as follows:

(1) With respect to the 1959 article by Dr. B. Calesnick (Reference No. 1) the advertisement gives the general impression that the author minimized the potential dangers of Esidrix, although he, in fact, stressed the potential dangers of the drug, particularly the side effect of potassium depletion; and further the advertisement misrepresents both the extent of initial transient hypokalemia observed by the author by stating that it was noted in a "few patients", whereas the author does not so limit its occurrence, and the effect of continued medication on potassium level by stating that the potassium levels returned to "normal" with continued medication, whereas the author reported only a "trend toward a return to the control level" with continuous medication.

(2) With respect to the 1959 article by Drs. Kemp and Findley (Reference No. 2), the advertisement misleadingly implies that in all of the 30 patients in that study serum potassium levels were slightly elevated and that danger of a lowered blood potassium in all those patients was non-existent, whereas serum electrolyte studies were made on only 18 patients and, although the average serum potassium level showed a slight increase after 10 days of Esidrix therapy, five patients showed a decrease in serum potassium and one of the five was diagnosed as having hypokalemia.

COUNTS III AND IV

1. The monograph relating to the drug Esidrix in the 1965 edition of the Physicians' Desk Reference omits the caution statement on combined therapy set out above at Count I, § 1(b).

2. The advertisement in the April 5, 1965 edition of the Journal of the American Medical Association failed to present a brief summary relating to side effects, contraindications and effectiveness of the drug Esidrix as follows:

(a) The advertisement fails to contain in brief summary a warning relating to the possibility of the drug's causing bowel lesions.

(b) The advertisement omits in brief summary the caution statement on combined therapy set out above at Count I, § 1(b).

———— ————,
United States Attorney.

———— ————,
Assistant United States Attorney.