were observed for any of the parameters evaluated. In all hens, feed and water intake, body weights, clinical health, egg production, and egg weights were evaluated. Histopathologic examinations were performed on H&E stained slides from each of the control and fenbendazole/kg body weight groups. No clinically significant effects related to the administration of Safe-Guard® AquaSol were observed for any of the parameters evaluated.

The margin of safety in laying hens was investigated in 144 chickens intended to become breeding chickens and for the treatment and control of adult A. galli and H. gallinarum.

The pivotal dose confirmation studies and field effectiveness studies demonstrated substantial evidence of effectiveness of Safe-Guard® AquaSol at the dose of 1 mg fenbendazole/kg body weight/day. The efficacy against adult A. galli (97.3%) was greater than 90%. A fourth dose confirmation study was conducted in the EU using 176 broiler breeder chickens at 4, 5, and 6 mg/kg body weight, respectively. The efficacy against adult A. galli was 99.4% and 98.7% and against H. gallinarum was 99.1% and 98.5%, respectively. A fifth effectiveness study was conducted in the US using 175 Cobb broiler breeder chickens (4 to 6 weeks old). The efficacy against adult A. galli was 99.4% and 99.6%, respectively. A field study was conducted in the EU using 143 broiler breeder chickens (10 to 12 weeks old). The efficacy against adult A. galli was 99.2%. A sixth field study was conducted in the US using 144 broiler breeder chickens at 5 mg/kg body weight, respectively. The efficacy against adult A. galli was 99.4%.

The above mentioned studies conducted using different experimental designs and under various field conditions demonstrated that Safe-Guard® AquaSol met the essential requirements for the use of fenbendazole in chickens for the treatment and control of adult A. galli and H. gallinarum.

In broiler chickens, replacement chickens intended to become breeding chickens and for the treatment and control of adult A. galli and H. gallinarum. Safe-Guard® AquaSol was administered orally in drinking water to 176 broiler breeder chickens. This study was conducted in the EU using 176 broiler breeder chickens at 4, 5, and 6 mg/kg body weight, respectively. The efficacy against adult A. galli was 99.4% and 99.6%, respectively. A field study was conducted in the US using 144 broiler breeder chickens at 5 mg/kg body weight, respectively. The efficacy against adult A. galli was 99.4%.

The above-mentioned studies conducted using different experimental designs and under various field conditions demonstrated that Safe-Guard® AquaSol met the essential requirements for the use of fenbendazole in chickens for the treatment and control of adult A. galli and H. gallinarum.