Food and Drug Administration, HHS

§ 310.547 Drug products containing quinine offered over-the-counter (OTC) for the treatment and/or prevention of malaria.

(a) Quinine and quinine salts have been used OTC for the treatment and/or prevention of malaria, a serious and potentially life-threatening disease. Quinine is no longer the drug of choice for the treatment and/or prevention of most types of malaria. In addition, there are serious and complicating aspects of the disease itself and some potentially serious and life-threatening risks associated with the use of quinine at doses employed for the treatment of malaria. There is a lack of adequate data to establish general recognition of the safety and effectiveness of colloidal silver ingredients or silver salts for OTC use in the treatment or prevention of malaria. Therefore, quinine or quinine salts cannot be safely and effectively used for the treatment and/or prevention of malaria except under the care and supervision of a doctor.

(b) Any OTC drug product containing quinine or quinine salts that is labeled, represented, or promoted for the treatment and/or prevention of malaria is regarded as a new drug within the meaning of section 201(p) of the act, for which an approved application or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for OTC use for the treatment and/or prevention of nocturnal leg muscle cramps is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) After February 22, 1995, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

[59 FR 43252, Aug. 22, 1994]

§ 310.548 Drug products containing colloidal silver ingredients or silver salts offered over-the-counter (OTC) for the treatment and/or prevention of disease.

(a) Colloidal silver ingredients and silver salts have been marketed in over-the-counter (OTC) drug products for the treatment and prevention of numerous disease conditions. There are serious and complicating aspects to many of the diseases these silver ingredients purport to treat or prevent. Further, there is a lack of adequate data to establish general recognition of the safety and effectiveness of colloidal silver ingredients or silver salts for OTC use in the treatment or prevention of any disease. These ingredients and salts include, but are not limited to, silver proteins, mild silver protein, strong silver protein, silver, silver ion, silver chloride, silver cyanide, silver iodide, silver oxide, and silver phosphate.

(b) Any OTC drug product containing colloidal silver ingredients or silver salts that is labeled, represented, or promoted for the treatment and/or prevention of any disease is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) for which an approved application or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug application, such product is also misbranded under section 502 of the act.

[63 FR 13528, Mar. 20, 1998]
(c) Clinical investigations designed to obtain evidence that any drug product containing colloidal silver or silver salts labeled, represented, or promoted for any OTC drug use is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs as set forth in part 312 of this chapter.

(d) After September 16, 1999, any such OTC drug product containing colloidal silver or silver salts initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

[64 FR 44658, Aug. 17, 1999]

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

Subpart A—General Provisions

Sec.
312.1 Scope.
312.2 Applicability.
312.3 Definitions and interpretations.
312.6 Labeling of an investigational new drug.
312.7 Promotion of investigational drugs.
312.8 Charging for investigational drugs under an IND.
312.10 Waivers.

Subpart B—Investigational New Drug Application (IND)

312.20 Requirement for an IND.
312.21 Phases of an investigation.
312.22 General principles of the IND submission.
312.23 IND content and format.
312.30 Protocol amendments.
312.31 Information amendments.
312.32 IND safety reporting.
312.33 Annual reports.
312.38 Withdrawal of an IND.

Subpart C—Administrative Actions

312.40 General requirements for use of an investigational new drug in a clinical investigation.
312.41 Comment and advice on an IND.
312.42 Clinical holds and requests for modification.
312.44 Termination.
312.45 Inactive status.
312.47 Meetings.
312.48 Dispute resolution.

Subpart D—Responsibilities of Sponsors and Investigators

312.50 General responsibilities of sponsors.
312.52 Transfer of obligations to a contract research organization.
312.53 Selecting investigators and monitors.
312.54 Emergency research under §30.24 of this chapter.
312.55 Informing investigators.
312.56 Review of ongoing investigations.
312.57 Recordkeeping and record retention.
312.58 Inspection of sponsor’s records and reports.
312.59 Disposition of unused supply of investigational drug.
312.60 General responsibilities of investigators.
312.61 Control of the investigational drug.
312.62 Investigator recordkeeping and record retention.
312.64 Investigator reports.
312.65 Assurance of IRB review.
312.66 Inspection of investigator’s records and reports.
312.69 Handling of controlled substances.
312.70 Disqualification of a clinical investigator.

Subpart E—Drugs Intended to Treat Life-threatening and Severely-debilitating Illnesses

312.80 Purpose.
312.81 Scope.
312.82 Early consultation.
312.83 Treatment protocols.
312.84 Risk-benefit analysis in review of marketing applications for drugs to treat life-threatening and severely-debilitating illnesses.
312.85 Phase 4 studies.
312.86 Focused FDA regulatory research.
312.87 Active monitoring of conduct and evaluation of clinical trials.
312.88 Safeguards for patient safety.

Subpart F—Miscellaneous

312.110 Import and export requirements.
312.120 Foreign clinical studies not conducted under an IND.
312.130 Availability for public disclosure of data and information in an IND.
312.140 Address for correspondence.
312.145 Guidance documents.

Subpart G—Drugs for Investigational Use in Laboratory Research Animals or in Vitro Tests

312.160 Drugs for investigational use in laboratory research animals or in vitro tests.

Subpart H [Reserved]