

EXCLUSION OF QUINOLONE DERIVATIVES AND VETERINARY ANTIBIOTIC PRODUCTS FROM THE BFAD BATCH CERTIFICATION REQUIREMENT

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Section 11 (m) of RA 3720 as amended, prohibits the release for sale or distribution of antibiotic drug without Batch Certification. Antibiotic drug is defined by Section 22 (a) of the same Act as "any drug intended for use by man containing any quantity of any chemical, substance which is produced by microorganisms which has the capacity to inhibit or destroy microorganism in dilute solution (including the chemically synthesized equivalent of any such substance)."

Quinolone derivatives (ciproflocacin, difloxacin, enoxacin, fleroxacin, nalidixic acid, norfloxacin, ofloxacin, perfloxacin, sparfloxacin) and veterinary antibiotic products therefore do not fall squarely within the aforecited definition of antibiotic drug that is required to be batch certified. The said products may be released for sale or distribution without BFAD batch certification.

Wherefore, effective September 15, 1996, BFAD has stopped issuing batch certification for quinolone derivatives and veterinary antibiotic products.

This is for your information and reference.

Adopted: 1 Oct. 1996

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