

INTRODUCTION

On November 16, 1988, the President of the United States signed into law the Generic Animal Drug and Patent Restoration Act (GADPTRA). Among its major provisions, the Act extends eligibility for submission of Abbreviated New Animal Drug Applications (ANADAs) to all animal drug products approved for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act.

The Act also requires that each sponsor of an approved animal drug product submit to the FDA certain information regarding patents held for the animal drug or its method of use. The Act requires that this information, as well as a list of all animal drug products approved for safety and effectiveness, be made available to the public. This list must be updated monthly under the provisions of the Act.

This publication, which is known as the “Green Book”, was first published in January of 1989. Updates have been added monthly since then. The list is published in its entirety each January.

There are eight sections in the publication. The first lists approved drug products; subsections being sorted by tradename and then by NADA number. The second section lists active ingredients and each approved product containing that active ingredient. Sections one and two will not contain products voluntarily withdrawn by their sponsor. The third section lists patent information as provided by the sponsors of approved animal drug products. Products voluntarily withdrawn will appear in this section if they have unexpired patents.

The five remaining sections provide additional information not specifically required by the Act, but may be useful to potential sponsors of ANADAs. Section four lists exclusivity periods granted for new uses or claims approved subsequent to enactment of GADPTRA. Section five lists any approved products that are currently the subject of a Notice of Hearing and thus may not be used as a basis of an ANADA. Section six lists animal drug products whose approval has been voluntarily withdrawn by their sponsors since GADPTRA was enacted. Products listed in this section may be used as a basis of an ANADA if their withdrawal was not for safety or effectiveness reasons. Section seven lists the actions on ANADA suitability petitions that have been received by the FDA since the enactment of GADPTRA. Section eight is reserved for monthly updates.

Comments or questions concerning the list or provisions of the GADPTRA should be addressed in writing to:

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