§ 121.1267 Benzene Hexachloride (HBC)

A tolerance of 5 parts per million is established for residues of the insecticide benzene hexachloride (HBC) in dehydrated peppers (paprika), resulting from application of the insecticide to growing peppers.

EDWIN L. JOHNSON,
Acting Deputy Assistant Administrator for Pesticide Programs.

[FED Reg. 50:5056 Filed 3-5-75; 3:45 am]

SUBCHAPTER C—DRUGS
PART 135—NEW ANIMAL DRUGS
PART 135a—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Tylosin

The Commissioner of Food and Drugs has evaluated a supplemental new animal drug application (97-7887V) filed by Blair Milling and Elevator Co., Inc., Atchison, KS 66002, proposing safe and effective use of a tylosin premix in the manufacture of swine feed. The application is approved.

To facilitate referencing, the firm is being assigned a sponsor code number and placed in the list of firms in 21 CFR 135.501(c).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(1), 82 Stat. 347; 21 U.S.C. 356b(1)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 135 and 135a are amended as follows:

1. In § 135.501(c) by adding a new sponsor as follows:

§ 135.501 Names, addresses, and code numbers of sponsors of approved applications.

(c) * * *

Code No. * * *

135

Firm name and address
Blair Milling & Elevator Co., Inc., 1000 Main St., Atchison, KS 66002.

2. In § 135.10 by adding a new paragraph (b) to read as follows:

§ 135.10 Tylosin.

(b) * * *

(1) Approvals.

(2) 0.4 gram per lb., Item 4.

Effective date. This order shall be effective March 6, 1975.

(3) Sec. 512(1), 82 Stat. 347; 21 U.S.C. 356b(1))


C. D. Van Houweling,
Director, Bureau of Veterinary Medicine.

PART 135—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Clortetracycline, Penicillin, Sulfathiazole

The Commissioner of Food and Drugs has evaluated a supplemental new animal drug application (32-077V) filed by Diamond Shamrock Chemical Co., Newark, NJ 07105, proposing safe and effective use of a premix containing 40 grams of clortetracycline hydrochloride, 40 grams of sulfathiazole, and 20 grams of penicillin per pound for feeding swine feed. The supplemental application is approved.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(1), 82 Stat. 347; 21 U.S.C. 356b(1)) and under authority delegated to the Commissioner (21 CFR 2.120), § 135.58(b) is amended by designating the current text as paragraph (b) (1) and adding paragraph (b) (2). As revised, paragraph (b) reads as follows:

§ 135.58 Clortetracycline, procaine penicillin, and sulfathiazole.

(b) Approvals.

(1) Premix level of 20 grams of clortetracycline hydrochloride per pound, 20 grams of sulfathiazole per pound, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound, has been granted for sponsor approval by code No. 025 in § 135.501(c) of this chapter.

(2) Premix level of 40 grams of clortetracycline hydrochloride, 40 grams of sulfathiazole, and procaine penicillin, equivalent to 20 grams of penicillin per pound has been granted to code No. 025 in § 135.501(c) of this chapter.

Effective date. This order shall be effective on March 6, 1975.

(3) Sec. 512(1), 82 Stat. 347; 21 U.S.C. 356b(1))


C. D. Van Houweling,
Director, Bureau of Veterinary Medicine.

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE
PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Removal of Naltrexone From Control

A Notice of Proposed Rulemaking by the Administrator of the Drug Enforcement Administration, dated December 3, 1974, was published in the Federal Register on Monday, December 9, 1974 (39 FR 42918). This notice proposed amending § 1308.14(b) of Title 21 of the Code of Federal Regulations so as to remove naltrexone from control under Schedule II of the Controlled Substances Act.

In designating reasons for this proposed rulemaking, the notice stated that the Administrator has found that naltrexone has a currently accepted medical use in treatment in the United States, and does not have sufficient potential for abuse or abuse liability to justify its continued control in any schedule under the Act.

The Administrator has, in fact, made no finding that naltrexone has a currently accepted medical use in treatment in the United States, and the appearance of such finding in the December 3, 1974, notice of proposed rulemaking was inadvertent. That finding was, therefore, not relied on as a reason for proposing to remove naltrexone from Schedule II. The December 9, 1974, notice provided that comments and objections regarding the proposed rulemaking could be submitted no later than January 8, 1975. None were received.

In view of the fact that no comments, objections or requests for hearing were received, the proposed order was based upon the investigations and review of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and 201(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a) and 811(b)). The Administrator of the Drug Enforcement Administration finds that naltrexone has no currently accepted medical use, and does not have sufficient potential for abuse or abuse liability to justify its continued control in any schedule under the Act.

Therefore, under the authority vested in the Attorney General by section 201

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RULES AND REGULATIONS

(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Administrator of the Drug Enforcement Administration by § 610 of Title 28 of the Code of Federal Regulations, the Administrator hereby orders that Title 21 of the Code of Federal Regulations (CFR) be amended by revising § 1308.12 (b) (1) to read as follows:

§ 1308.12 Schedule II.

(1) Opium and opalate, and any salt, compound, derivative, or preparation of opium or opalate, excluding naloxone and its salts, and excluding naltrexone and its salts, but including the following:

<table>
<thead>
<tr>
<th>Compound</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Raw opium</td>
<td>9000</td>
</tr>
<tr>
<td>2 Opium extract</td>
<td>9010</td>
</tr>
<tr>
<td>3 Opium fluid extract</td>
<td>9020</td>
</tr>
<tr>
<td>4 Powdered opium</td>
<td>9030</td>
</tr>
<tr>
<td>5 Granulated opium</td>
<td>9040</td>
</tr>
<tr>
<td>6 Tincture of opium</td>
<td>9050</td>
</tr>
<tr>
<td>7 Apomorphine</td>
<td>9060</td>
</tr>
<tr>
<td>8 Codeine</td>
<td>9070</td>
</tr>
<tr>
<td>9 Ethylmorphine</td>
<td>9100</td>
</tr>
<tr>
<td>10 Diaporphine hydrochloride</td>
<td>9090</td>
</tr>
<tr>
<td>11 Hydrocodone</td>
<td>9110</td>
</tr>
<tr>
<td>12 Hydromorphone</td>
<td>9120</td>
</tr>
<tr>
<td>13 Metadone</td>
<td>9130</td>
</tr>
<tr>
<td>14 Mepiphenyl</td>
<td>9140</td>
</tr>
<tr>
<td>15 Oxycodone</td>
<td>9143</td>
</tr>
<tr>
<td>16 Oxymorphone</td>
<td>9150</td>
</tr>
<tr>
<td>17 Thebaine</td>
<td>9133</td>
</tr>
</tbody>
</table>

This order is effective on March 6, 1975.


JOHN R. BARTELS, JR.,
Administrator,
Drug Enforcement Administration.
[FR Doc. 75-6259 Filed 3-5-75; 8:45 am]

Title 27—Alcohol, Tobacco Products and Firearms

CHAPTER I—BUREAU OF ALCOHOL, TOBACCO AND FIREARMS, DEPARTMENT OF THE TREASURY

[T.D. APT-11]

PART 6—INDUCEMENTS FURNISHED TO RETAILERS

Inside Signs Furnished to Retailers of Wine by Industry Members

The purpose of these amendments to 27 CFR Part 6, Inducements Furnished to Retailers, is to increase the maximum value of advertising materials that may be given, rented, loaned, or sold to a retailer of wine by an industry member engaged in business as a rectifier, blender, producer, bottler, importer, or wholesaler of wine. The amendments also correct an editorial error in another section concerning exceptions from the inducement provisions.

SUMMARY OF NOTICE

The advertising limitation for wine at the retail level was established at $10 in 1936; and after public hearings held in 1968, the limitation was increased to $15 due primarily to the increase in the cost of advertising materials. The Wine Institute, a trade association representing numerous wine producers in California, petitioned the Bureau to increase the advertising limitation several months ago, and on that basis a notice of proposed rulemaking was published in the Federal Register on March 17, 1974. (39 FR 33359, proposing an increase from $15 to $90 in 27 CFR 6.23a). The notice also included a proposal for correction of an editorial error in 27 CFR 6.31. Interested persons were afforded an opportunity to comment on the proposed amendments and due consideration was given to all comments received in response to the notice.

SUMMARY OF COMMENTS

A total of seven comments were received on the proposals. All persons who commented on the proposed change to 27 CFR 6.21 fully supported the amendment. However, there was wide disparity among the comments regarding the proposed amendment of 50% of the current $15 limitation. The disposition to the proposed advertising increase was presented in comments submitted by two small wineries. The basis for the opposition was, first, that the rule would permit large wineries to gain an advertising advantage at the retail level over small wineries and, second, that there seemed to be no justification for increasing the limitation beyond the proposed 50%.

Four comments in support of the proposals were submitted by industry members and industry associations. Increased costs of advertising materials and labor were the major justifications provided by those supporting the proposed increase. The data presented in these comments reflected increases of up to 100% for material costs and labor costs. In one comment from an industry association, it was also noted that most industry sources predict an increase of 100% for both material and production costs within the next five years.

Representatives of one winery supported the limitation increase but asked that the total value of materials furnished by an industry member engaged in business as a rectifier, blender, producer, bottler, importer, or wholesaler of wine at any time in any retail establishment be limited to $30 for any one brand. In their opinion, without such a brand limitation, the economic impact upon the small brand owner would make him non-competitive in the marketplace. In essence, they indicated that many small family-owned businesses simply could not afford the cost of creating individual displays costing $90.

As stated in the notice, in addition to data relative to increases in the cost of advertising material and labor, the Bureau was also interested in ascertaining if there were other factors which justified an increase in the present limitation. With regard to trade customs, one comment received indicated that there has been a significant increase in the number of wines marketed in the United States in recent years, primarily special natural wines; and this change in the range of wines marketed has necessitated changes in advertising methods. Another comment received indicated that changes in both merchandising and distribution patterns for wine require broader coverage with more advertising materials.

CHANGES PURSUANT TO NOTICE

Support for an increase in the limitation proposed to be the Bureau was well documented and provided data which showed that along with an increase in the cost of advertising materials, there has been a change in certain trade practices in the wine industry, specifically changes in merchandising and advertising practices for wine. However, based on independent interpretation of economic indicators, the intent of the Federal Alcohol Administration Act, and the evaluation of all comments concerning the notice of proposed rulemaking, the Bureau has found that an increased advertising limit of $90 is not justifiable, and an increase in the limitation to $75 is more realistic and equitable. This increase will recognize the impact of inflation on the costs of advertising materials and labor and provide for advertising consistent with modern wine merchandising. With respect to the $30 brand limitation requested by one winery, the Bureau feels that such a limitation would not recognize the effect of inflation over the past six years, and further that such a limitation would be extremely difficult to enforce, and is, therefore, not adopting a limitation of that type.

In view of the foregoing, the proposed regulations are hereby adopted, subject to the change mentioned above.

Prosemary 1. Section 6.21 is amended to include a reference to § 6.23b, in the case of wine. As amended, § 6.21 reads as follows:

§ 6.21 General.

An industry member may furnish to a retailer, under the conditions and within the limitations prescribed, the equipment, signs, supplies, or other things of value specified in § 6.22-6.31. Fined. That, except for such alcoholic beverages as may reasonably be required to complete a window or other interior display furnished pursuant to § 6.23, § 6.23a, or § 6.23b, such furnishing is not conditioned directly or indirectly on the purchase of distilled spirits, wine, or malt beverages.

Par 2. Section 6.23b is amended by increasing the limitation to $75. As amended, § 6.23b reads as follows:

§ 6.23b Inside signs; wine.

Signs, posters, placards, decals, devices, decorations, or graphic displays, bearing advertising matter and for use in the windows or elsewhere in the interior of a retail establishment, may be given, rented, loaned, or sold to a retailer by an industry member engaged in business as a rectifier, blender, producer, bottler, importer, or wholesaler of wine, if they have no value to the retailer except as advertisements and if the total value of all such materials furnished by any industry member and in use at any one time in any retail establishment does.