

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Matter of: )  
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FDA DOCKET: 00N-1571

**ORDER**

By Motions to Strike<sup>1</sup> filed January 27, 2003 each side to this proceeding seeks to strike extensive portions of the others testimony and evidence based on various assertions of inadmissibility. After review of the Replies, filed February 10, 2003 and the controlling authorities, it has been determined that certain general guidelines will be used in ruling on the motions.

- 1) Qualified expert witnesses are free to render opinions, within their areas of expertise, using a wide range of information in support thereof. However, expert witnesses are not free to introduce unsupported facts into the record.
- 2) Risk/benefit evidence is relevant only to the extent it deals with human health effects, i.e. whether the human health benefits of using the drug outweigh the human health risks from use of the drug.
- 3) Evidence as to the existence of drug resistant strains absent the use of Baytril, as compared with the existence of such strains with such use, is relevant to the threshold issue of establishing a reasonable basis for calling the safety of the drug into question.
- 4) Evidence of the availability and efficacy of alternative drugs is relevant only in so far as it relates to "2)" above.
- 5) Economic and environmental evidence is not relevant to the issues in this proceeding.

<sup>1</sup> The Animal Health Institute has adopted Respondent's Motions to Strike.

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OR31

**It is ordered** that the Motions to Strike are granted in part. The material identified below is stricken from the evidentiary record<sup>2</sup> in this proceeding as irrelevant, immaterial, unreliable or unduly repetitious:

The Respondent's Motion to Strike testimony and exhibits set forth in Appendix D thereto (relating to the Sentinel County Study) is granted solely for the reason that relevant information requested by Respondent was not furnished by the Center for Veterinary Medicine (CVM) in a timely manner.<sup>3</sup>

Exhibit No. G-300.

Exhibit No. G-320.

Exhibit No. G-1451:

P. 3, sentence beginning on line 31 through line 33.

P. 7, lines 3-8.

P. 9 line 48 through P. 10, line 2.

Exhibit No. G-1454, P.14, from "Although..." on line 45 through "...source." on line 47.

Exhibit No. G-1462.

Exhibit No. G-1454:

P. 14, two sentences beginning on line 43.

P. 15, sentence beginning on line 23.

Exhibit No. G-1457, P. 9, sentence beginning on line 34.

Exhibit No. G-1461 entirely.

Exhibit No. G- 1463, P.7, from "They..." on line 35 through "...12 deaths." on line 37.

Exhibit No. G- 1468, P.11, line 13 from "It is..." through line 15.

Exhibit No. G- 1469, P. 6, line 12 from "The most..." through "...usefulness" on line 17.

Exhibit No. G-1471.

Exhibit No. G- 1480:

P.5, lines 18 through 23, lines 36 through 39.

P.10, lines 15 through 22.

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<sup>2</sup> Material stricken from the evidentiary record remains in the Administrative Record.

<sup>3</sup> The ruling is without prejudice to the re-submission of the testimony and exhibits at the oral phase of this proceeding.

Exhibit No. G-1495 and all references thereto.

Exhibit No. G-1784.

Exhibit No. B-213

Exhibit No. B-1900:

- P. 2, sentence beginning on line 42.
- P. 3, sentence beginning on line 3.
- P. 4, sentence beginning on line 26.
- P. 17, lines 29 through 44.
- P. 24, sentence beginning on line 5.
- P. 42, sentence beginning on line 9.
- P. 43, sentence beginning on line 12.
- P. 47, lines 9 through 16.
- P. 48, sentence beginning on line 6.

Exhibit No. B-1901:

- P. 5, line 14 through P. 6, line 20.
- PP. 80 and 81.

Exhibit No. B-1902, P. 40, sentence beginning on line 5 through "...observed." on line 16.

Exhibit No. B-1903:

- P. 6, line 8 through P. 7, line 3.
- P. 8. Figure 1.
- P. 11, lines 13 through 16.

Exhibit No. 1904:

- P. 4, line 5 through P. 6, line 16.
- P. 9, line 3 through the table preceding line 6.
- P. 9, line 10 through P. 10, line 2.
- P. 12, lines 6 through 9 and line 15 through Figure 1 on P. 13.
- P. 17, line 22 through P. 19, line 11, including footnote 6.
- P. 24, line 16 through P. 25, line 6.

Exhibit No. B-1906, P.10, line 15 through "...was mentioned." on P. 11, line 3.

Exhibit Nos. B-1907, B-1918 and B-1919 entirely.

Exhibit No. B-1908:

- P. 18, sentence beginning on line 8.

P. 21, sentence beginning on line 3.  
P. 23, sentence beginning on line 22, through "...sources." on P.24, line 10.  
P. 35, line 22 through P. 36, line 4.

Exhibit No. B-1911:

P. 5, lines 8 through 16.  
P. 7, sentence beginning on line 1, through line 18.  
P. 8, line 3 through P. 9, line 8.  
P. 12, line 14 through P. 13, line 16.  
P. 13, sentence beginning on line 21, through P.14, line 4.  
P. 15, lines 1 through 17.

Exhibit No. B-1912:

P.6, line 10 through P. 7, line 22.  
P. 11, line 3 through P. 12, line 2.  
P. 12, sentence beginning on line 8, through line 15.  
P. 13, sentence beginning on line 5, through P. 15, line 13.  
P. 18, sentence beginning on line 3.  
P. 18, sentence beginning on line 6 through P. 19, line 8.  
P. 27, line 1 through P. 30, line 2.  
P. 30, sentence beginning on line 7 through P. 31, line 14.  
P. 52 through P. 61 (Attachment # 2).

Exhibit No. B-1913:

P. 6 and P. 25, ¶¶ 6.1.  
P. 7, lines 12 through 18 and P. 26, ¶ 1.4.  
P. 10, ¶¶ 1.24, 1.25, 1.26, 1.27, 1.30 and the same ¶¶ on P. 28.  
P. 19, sentence beginning on line 3 through line 9.  
P. 21, sentence beginning on line 16.  
P. 53, ¶¶ 6.1, 6.2 and 6.3.

Exhibit No. B-1914:

P. 17, lines 13 through 15.  
P. 19, line 4 through P. 20, line 22.  
P. 23, three sentences beginning on line 14 and ending on line 19.  
P. 25, two sentences on lines 16 through 18.  
P. 28, lines 6 through 8.  
P. 29, line 15 through P. 31, line 20.  
P. 32, lines 1,2,3,5 and 7.

Exhibit No. B-1915:

P. 4, sentence beginning on line 12.  
P. 5, sentence beginning on line 10.

Exhibit No. B-1916:

P. 14, sentence beginning on line 18 through "...unsafe..." on line 19.

Exhibit No. B-1917:

- P. 8, line 14 through "...substantial." on line 15.
- P. 11, sentence beginning on line 13.
- P. 20, lines 16 through 21.
- P. 21, lines 3 through 5 and line 10.
- P. 15, sentence on line 18.

Exhibit No. A-199:

- P. 9, lines 8 through 24.
- P. 21, two sentences beginning on line 16.
- P. 22, line 6 through P. 24, line 20.
- P. 24, line 22 through P. 25, line 21.
- P. 26, line 16 through "...resistance." On P. 27, line 8.
- P. 28, lines 9 through 26.
- P. 29, lines 1 through 16.
- P. 31, from "...and in so..." on line 11 through end of sentence on line 13.
- P. 34, Line 19 through P. 35, line 26.
- P. 36, line 1 through P. 38, line 27.
- P. 39, lines 5 through 12.
- P. 41, line 26 through P. 42, line 10.
- Attachments 5, 6 and 7.

Exhibit No. A-200:

- P. 10, line 17 through P.12, line 2.
- P. 33, line 18 through P. 34, line 7.
- P. 54, sentence beginning on line 13.
- P. 66, line 17 through P. 67, line 2.
- P. 67, sentence beginning on line 17 through P. 68, line 4.

Exhibit No. A-201:

- P. 4, sentence beginning on line 2.
- P. 5, sentence beginning on line 16.
- P. 12, sentence beginning on line 2.
- P. 13, line 10 through P. 14, line 7.
- P. 15, lines 12 through 23.
- P. 18, line 9 through P. 20, line 3.
- P. 31, sentence beginning on line 4 through line 16.
- P. 32, line 17 through P. 33.
- P. 36, sentence beginning on line 3.

Exhibit No. A-202:

- P. 7, sentence beginning on line 19.
- P. 9, line 22 through P. 10, line 11.
- P. 12, sentence beginning on line 10 through P. 13, line 2.

- P. 13, sentence beginning on line 6 through "...die," on line 15.
- P. 14, sentence beginning on line 10 through "...birds." on line 19.
- P. 15, sentence beginning on line 18 and Figure 4 on P. 16.
- P. 17, lines 12 through 15.
- P. 28, sentence beginning on line 15.
- P. 29, sentence beginning on line 19 through P. 30, line 10.
- P. 30, sentence beginning on line 12.

Exhibit No. A-203:

- P. 4, line 13 through P. 7, line 15.
- P. 8, line 14 through P. 10, line 28.
- P. 11, three full sentences beginning on line 3.
- P. 12, line 1 through P. 13, line 20.
- P. 13, sentence beginning on line 22.
- Beginning with the chart on P. 17 through P.21.

Exhibit No. A-204:

- P. 8, lines 19 through 21.
- P. 15, sentence beginning on line 17 through P.16, line 3.
- P. 16, line 8 through "... regulation." on P. 27, line 22.
- P. 28, sentence beginning on line 3 through P. 29, line 18.
- P. 30, line 19 through P. 37, line 16.
- P. 51, sentence beginning on line 14 through P. 56, line 18.
- P. 59, lines 3 through 8.

It is further **Ordered** that the Motions to Strike are in all other respects denied as being unsubstantiated or relating more to the weight to be given the evidence assailed than to the admissibility thereof.

And it is Further **Ordered** that any request for the opportunity to submit rebuttal evidence must be filed on or before March 17, 2003 with a detailed justification therefor.

Dated this 3<sup>rd</sup> of March, 2003

s/s Daniel J. Davidson  
Daniel J. Davidson  
Administrative Law Judge