

Case #7029 (01/20/2022)

Merck Animal Health

BRAVECTO®

Challenger: *Boehringer Ingelheim Animal Health USA, Inc.*

Product Type: *Pet Products*

Issues: *Product Performance*

Disposition: *Modified/Discontinued*

BBB NATIONAL PROGRAMS

NATIONAL ADVERTISING DIVISION

BOEHRINGER INGELHEIM ANIMAL
HEALTH USA, INC,

Challenger,

MERCK ANIMAL HEALTH,

Advertiser.

Case No. 7029

Filed 1/20/2022

- When making “apples-to-oranges” comparisons in order to highlight features or attributes of their products, the advertising should disclose the material differences between the products.

FINAL DECISION

I. Basis of Inquiry

The advertising industry established the National Advertising Division (“NAD”) and the National Advertising Review Board (“NARB”) in 1971 as an independent system of self-regulation designed to build consumer trust in advertising. NAD reviews national advertising in all media in response to third-party challenges or through inquiries opened on its own initiative. Its decisions set consistent standards for advertising truth and accuracy, delivering meaningful protection to consumers and leveling the playing field for business. Challenger *Boehringer Ingelheim Animal Health USA, Inc.* (“BI” or “Challenger”) challenged express and implied claims made by Advertiser *Merck Animal Health* (“Merck” or “Advertiser”) for its BRAVECTO(R) (*Bravecto*) flea and tick preventive for dogs. The following are representative of the claims that served as the basis for this inquiry:

A. Express Claims

- NexGard users will experience “a rejection in protection at week 5”.

B. Implied Claims

- BRAVECTO is “best in show,” i.e. better than NexGard at preventing flea and tick infestations when both products are used as directed.
- NexGard does not provide long lasting flea and tick prevention when used as directed.
- NexGard is ineffective, even when dosed according to the package directions, at preventing flea infestations after week 5.

II. Evidence Presented

The Challenger submitted the Declaration of Dean Daily, the Senior Associate Director, Pet Veterinary Technical Marketing for BI regarding dosing differences between *Bravecto* and BI's *NexGard* as well as the products' efficacy. The Challenger also submitted its Package Insert for *NexGard* and scientific literature regarding the active ingredients in *NexGard* and *Bravecto*.¹ In addition, the Challenger submitted an image of packaging for its own topical flea and tick control product Frontline Plus and marketing materials for the Advertiser's topical product Activyl.

The Advertiser submitted copies of the FDA labeling for both *Bravecto* and *NexGard*. The Advertiser also submitted the Challenger's own advertising which touts its product's dosing as an advantage because its "monthly dosing that's easy to coordinate with other medications" and noted that *NexGard's* "active ingredient works for a month, after which your dog is vulnerable to flea infestations again. That's why it's important to give your dog their flea protection on a regular schedule." The Advertiser also submitted Freedom of Information Summaries for both *Bravecto* and *NexGard*.

In addition, the Advertiser submitted a Declaration from Dr. Frank Guerino, the Executive Director of Global Pharmaceutical Development at Merck in response to the flea control-related data submitted by the Challenger. The Advertiser also submitted various other scientific literature, articles, and regulatory guidance regarding parasitic protection for animals and the efficacy of protection products and ingredients.²

III. Decision

The parties are competing manufacturers of, among other products, oral flea and tick preventatives for dogs. The Challenger argues that the Advertiser's television commercial conveys the false, misleading, and disparaging messages that *Bravecto* is more efficacious at killing fleas and ticks than *NexGard* or that *NexGard* fails to provide long lasting protection against fleas and ticks when used as directed. According to the Challenger, the only consumer-relevant difference between the two products is that *NexGard* is administered monthly while *Bravecto* is administered every 12 weeks.³

A. Challenged Advertising

The challenged advertising is the 30-second television commercial ("Best in Show") featuring a comparison of the *Bravecto* and *NexGard* products with the actor John Michael Higgins who starred

¹ Letendre, et al., *Vet Parasit.* 201 (2014) 190-97; Dryden, et al., *Parasites & Vectors* (2016) 9:365; Beugnet, et al., *Vet. Parasit.* 207 (2015) 297-301; Beugnet, et al., *Vet. Parasit.* 209 (2015) 142-145.

² A.A. Marchiondo et al., *World Association for the Advancement of Veterinary Parasitology (W.A.A.V.P.) second edition: Guidelines for evaluating the efficacy of parasiticides for the treatment, prevention, and control of flea and tick infestations on dogs and cats*, *Veterinary Parasitology* 194 (2013) 64-87; Lavan et al., *Dog owner flea/tick medication purchases in the USA*, *Parasites and Vectors* (2018); *Guidance for Industry, Effectiveness of Anthelmintics*, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (Oct. 11, 2001); European Medicines Agency, *Science Medicines Health, Guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats* (Jul. 14, 2016); FDA Letter to Inspire Pharmaceuticals, Inc., RE: NDA # 050810, *AzaSite*[®] (azithromycin ophthalmic solution) 1%, MACMIS #18525, Apr. 14, 2011; Credit Suisse, *Figure 92: Companion Animal Parasiticide Landscape* (Jul. 13, 2021); R. Armstrong, *Letter to the Editor, Veterinary Parasitology* (2015).

³ *Bravecto* is to be administered every 8 weeks for full protection against lone star ticks.

in the film “Best in Show.” Higgins states “Welcome. It’s time to see which chew is best in show for long-lasting flea and tick protection.” Higgins is depicted overseeing two dogs on each side of a fence. An image of *NexGard* packaging appears above the dog on the left-hand side of the screen, indicating that the dog was given *NexGard*. The dog on the right is similarly shown to have been given *Bravecto*. “Week 1” appears on the top left of the screen inside of a large circle. A disclosure appears on the bottom the screen stating “BRAVECTO Chews for Dogs kills fleas, prevents flea infestations, and kills ticks (black-legged tick, American dog tick, and brown dog tick) for 12 weeks. BRAVECTO Chews also kills lone star ticks for 8 weeks. NexGard is approved for 30 days.”

Higgins follows with “we may be here for weeks, even months,” while winking at the camera. The next frame shows “Week 5” on the top left of the screen inside of a large white circle indicating the passage of time. The dog on the left that had been given *NexGard* is shown scratching for four to five seconds suggesting that it has been bitten by fleas while Higgins exclaims “Holy smokes, a rejection in protection at week 5!” The *Bravecto*-treated dog puts its paws up on the fence to look into the other yard, while wagging its tail.

The commercial then continues with Higgins saying “But Bravecto just won’t quit.” The *Bravecto*-treated dog is shown hopping in the air happily, as the circle on the upper left of the screen is updated to “Week 8” to illustrate the further passage of time.

Higgins then states, “Let’s hear from our veterinarian expert.” An actor portraying a veterinarian appears and states, “Bravecto is our clear winner. 12 weeks of powerful protection, nearly 3 times longer than any other chew” while the *Bravecto*-treated dog continues to wag its tail and the *NexGard*-treated dog places its paw over its eyes in apparent disappointment. Higgins states, “Now that’s what I’m talking about! Bravo, Bravecto. Bravo,” while the *Bravecto*-treated dog sits on top of a winner’s podium. The veterinarian stands to the side holding a trophy labeled “#1 Long Lasting Chew.”

The Challenger argued that the challenged claims should either be discontinued, or at a minimum, modified to make clear that *NexGard* is to be administered monthly to achieve long-lasting flea protection. Specifically, the Challenger maintained that the commercial makes an unfair apples-to-oranges comparison of the efficacy of a 12-week chew and a monthly chew by focusing on the difference in efficacy between weeks 5 to 12, while failing to explain the dosing difference. According to the Challenger, this violates the rule that advertisers comparing dissimilar products must disclose the material differences between the products being compared and that failing to adequately disclose material information regarding the differences between the compared products can render the comparison misleading to consumers. According to the Challenger, the commercial compares products that differ in one material respect: dosing instructions. The Challenger argued that the advertisement is expressly comparative, naming both *NexGard* and *Bravecto* specifically. In comparing *NexGard* to *Bravecto*, the Challenger argued that the Advertiser fails to disclose the fundamental difference in the product’s dosing.

The Challenger noted that the voiceover says nothing about the fact that *NexGard* is directed to be given every month. The Challenger also argued that the disclosure that appears on the bottom of the

screen is ineffective.⁴ The Challenger asserted that the disclosure is not conspicuous, is presented in faint letters on top of moving images that would distract a viewer and that the disclosure with respect to *NexGard* is buried inside a dense paragraph of text and thus difficult to read. The Challenger also argued that the language of the disclosure itself is ineffective at communicating the material dosing difference between the two products. The Challenger contended that the statement that "NexGard is approved for 30 days" does not clearly convey the material fact that the product is directed to be administered every month, and that one can simply re-dose each month, as directed, to obtain similar or better efficacy as *Bravecto*. At best, the Challenger argued that the Best in Show commercial's disclosure is ambiguous and is subject to a number of interpretations, including the interpretation that *NexGard* can only offer a maximum of 30 days of flea and tick protection.

The Challenger also maintained that the claim that dogs treated with *NexGard* will experience a "rejection in protection at week 5" is false. While the product is labeled to be administered monthly, the Challenger maintained that a dog treated with *NexGard* will not experience a "rejection in protection" after 5 weeks.⁵

According to the Challenger, the Best in Show commercial also implies that *Bravecto* is more effective than *NexGard* at killing fleas and ticks, even when both products are dosed as directed. In the context presented in the advertisement, the Challenger argued that one reasonable interpretation of the commercial is that *Bravecto* is more effective at protecting dogs from fleas and ticks, not just that *Bravecto* lasts longer.⁶ The Challenger also contended that the commercial disparages *NexGard* by implying that it fails to provide long-lasting flea and tick protection or that it is ineffective at preventing flea infestations after 5 weeks, even when used as directed.

The Advertiser countered that its commercial provides a truthful and accurate comparison of the two products' duration of action, without making any comparative efficacy representations. According to

⁴ The disclosure states: "BRAVECTO Chews for Dogs kills fleas, prevents flea infestations, and kills ticks (black-legged tick, American dog tick, and brown dog tick) for 12 weeks. BRAVECTO Chews also kills lone star ticks for 8 weeks. NexGard is approved for 30 days."

⁵ The Challenger maintained that at 35 days after administration, *NexGard* demonstrates 100% efficacy against fleas as stated on its product labeling ("In a separate well-controlled laboratory study, *NexGard* demonstrated 100% effectiveness against adult fleas 24 hours post-infestation for 35 days."). The Challenger argued that the continued efficacy of afoxolaner at Day 35 and beyond is confirmed by pharmacokinetic studies, which show a long, linear elimination curve after administration. According to the Challenger, after 5 weeks, dogs treated with *NexGard* have been shown to have a blood concentration of the active ingredient, afoxolaner, to be effective against fleas through at least day 55 and therefore *NexGard* does not simply stop being effective against fleas after one month or even after 5 weeks. The Challenger argued that its *NexGard* product is efficacious against fleas after 5 weeks and that the label directions to dose monthly are based on the need for optimal performance against ticks. The Advertiser, however, noted that the FDA approved labeling of *NexGard* states that "On Day 28, *NexGard* was 81.1% effective 12 hours post-infestation" which is below the 90% effectiveness generally required to establish the efficacy of an antiparasitic product.

⁶ The Challenger argued that *NexGard* may be more effective than *Bravecto* at flea and tick prevention when each product is administered in accordance with the schedules described in their respective labels because the monthly dosing regimen of afoxolaner better maintains blood plasma concentrations of the active over time, when compared with a single pill-per 12 (or 8) week regiment for fluralaner and that, at a minimum, *NexGard* offer similar protection against fleas and ticks when used as directed. Accordingly, the Challenger argued that Merck cannot substantiate the reasonably-implied claim that *Bravecto* provides superior protection against fleas and ticks as compared to *NexGard*.

the Advertiser, the commercial provides material information regarding the differing duration of action for *Bravecto* and *NexGard*, based on the information provided in the products' FDA-approved labels. Merck noted the language in the disclosure that appears on the bottom of the screen during the commercial is based on information from the products' FDA-approved labeling that *Bravecto* is approved for use as a flea preventative on a 12-week schedule, while *NexGard* is approved for use for treating fleas on a one-month schedule.

The Advertiser maintained that several elements in the commercial reinforce the message that the commercial is comparing the relative duration of action of the two products. Specifically, the Advertiser argued that the commercial contains several pronounced oral, visual, and contextual cues to clearly convey that the commercial is comparing the duration of action of a dose of each product, including beginning the commercial with a reference to “long-lasting” relief, providing consistent visual illustrations of the passage of time, reiterating that “we could be here for weeks, even months,” displaying the relative dosing indications for the products without any comparative efficacy language, and utilizing multiple voiceover references to “weeks of” and “long-lasting” protection. According to the Advertiser, no reasonable consumer could understand the commercial to reference anything but the two products' relative duration of action.

B. Messages Conveyed

It is well-established that an advertiser is responsible for all reasonable interpretations of its claims conveyed by advertising, not simply the messages it intended to convey.⁷

NAD noted that the relative efficacy of the parties' products in terms of their preventing flea infestations is not in dispute. Rather, the sole issue here is whether the challenged commercial communicates a product distinction beyond a difference in duration or otherwise implies a claim of comparative superiority. As neither party submitted evidence to support its respective position concerning messages that consumers could reasonably take away from the Best in Show commercial, NAD used its own expertise to evaluate whether any implied messages were conveyed.⁸ In the absence of reliable consumer perception evidence, NAD routinely steps into the shoes of the reasonable consumer to determine the messages reasonably conveyed by an advertisement.⁹ In analyzing the messages conveyed by a particular advertisement, NAD typically reviews the totality or overall net impression created by an advertisement as a whole, including the words and the visual images, not merely words or phrases standing alone.¹⁰

Therefore, NAD considered whether the Best in Show commercial reasonably conveys the message that *Bravecto* provides more efficacious protection against fleas than *NexGard* or if the commercial conveys only a message about the two products' relative duration of action. NAD acknowledged that some elements of the challenged commercial, such as the depiction of the passage of time and the statement “nearly 3 times longer than any other chew,” are suggestive of a comparison of the two

⁷ *Johnson & Johnson Consumer Inc. (Neutrogena Personal Care Products)*, Report #6926, NAD/CARU Case Reports (June 2021).

⁸ *Bayer Healthcare, LLC (Aleve® Naproxen Sodium Tablets)*, Report #4418, NAD/CARU Case Reports (October 2005)

⁹ *Charter Communications, Inc. (Spectrum Mobile)*, Report #6940, NAD/CARU Case Reports (April 2021).

¹⁰ *Id.*

products' duration of action. The commercial also contains a disclosure on the bottom of the screen stating "BRAVECTO Chews for Dogs kills fleas, prevents flea infestations, and kills ticks (black-legged tick, American dog tick, and brown dog tick) for 12 weeks. BRAVECTO Chews also kills lone star ticks for 8 weeks. NexGard is approved for 30 days."

When viewed in its entirety, however, NAD determined that the commercial blends duration of action claims with a comparative superiority message and that one reasonable interpretation of the commercial is that *Bravecto* is superior to *NexGard* in protecting dogs from flea infestations.¹¹ Specifically, NAD noted that the commercial depicts product failure with the *NexGard* dog scratching for several seconds while Higgins states "Holy Smokes! A rejection in protection at week 5!" The commercial also depicts a veterinarian declaring *Bravecto* is "our clear winner" and presenting the *Bravecto*-treated dog with a "#1 Long Lasting Chew" trophy with the *NexGard*-treated dog covering its eyes with its paw. When viewed in its entirety, NAD determined that one reasonable interpretation of the commercial is that *Bravecto* is more effective than *NexGard* at protecting dogs from fleas and not merely that one dose of *Bravecto* lasts longer than one dose of *NexGard*.

1. "Apples-to-oranges" comparison

When making "apples-to-oranges" comparisons in order to highlight features or attributes of their products, the advertising should disclose the material differences between the products.¹² Here, NAD found that the challenged commercial did not clearly communicate the basis of the comparison, i.e., the difference in the products' respective duration of action.¹³ While the commercial contains a disclosure that appears on screen for several seconds, NAD determined that the disclosure did not clearly communicate the basis of the product comparison depicted in the commercial with the disclosure stating that *Bravecto* "kills fleas, prevents flea infestations, and kills ticks... for 12 weeks" while *NexGard* is "approved" for 30 days.

NAD has recognized that effective disclosures, regardless of format, must be "clear and conspicuous" such that the disclosure is "displayed in a manner that is readily noticeable, readable and/or audible, and understandable to the audience to whom it is directed."¹⁴ In order to assess the adequacy of the disclosure, NAD reviews "the size of the font, the duration that the disclosure appears on screen, the

¹¹ Any message that NAD finds to be implied by an advertisement need not be the only message conveyed or even the main message conveyed – it need only be one of the messages reasonably conveyed by the advertiser, even if unintentionally. Snapple Beverage Corporation (Snapple-A-Day Meal Replacement), Report #4132, NAD Case Reports (January 2004).

¹² Behr Process Corporation (Paints and Stains), Report #6148, NAD/CARU Case Reports (January 2018); Reckitt Benckiser LLC (Air Wick Scented Oil), Report #6283, NAD/CARU Case Reports (June 2019).

¹³ The disclosure states "BRAVECTO Chews for Dogs kills fleas, prevents flea infestations, and kills ticks (black-legged tick, American dog tick, and brown dog tick) for 12 weeks. BRAVECTO Chews also kills lone star ticks for 8 weeks. NexGard is approved for 30 days."

¹⁴ Bank of America (1-2-3 Cash Rewards Advertising Campaign), Report #5522, NAD/CARU Case Reports (November 2012)

extent to which it contrasts with the background, as well as surrounding visuals and sounds that may distract a viewer's attention away from the super (disclosure)."¹⁵

NAD found that the disclosure was not clear and conspicuous because it is in small print, in light font, against a dynamic background and the language itself is not easy to understand. The disclosure appears on screen, while Higgins is speaking, the dogs are shown side-by-side as well as individually, "Week 1" appears on the top left of the screen in much larger font, and the packaging for both the *Bravecto* and *Nexgard* appears prominently on screen. The disclosure also appears in small print, in white font against a dynamic background. As a general rule, NAD considers that visuals moving above or behind a small text message are likely to distract consumers' attention away from the intended message.¹⁶ NAD determined that the disclosure in this case was not sufficiently prominent for consumers to notice, read and understand the basis of the apples-to-oranges comparison being depicted in the commercial.¹⁷ For these reasons, NAD recommended that the Advertiser discontinue the commercial and take steps to ensure that when making an "apples-to-oranges" comparison between *Bravecto* and *NexGard*, that the material dosing difference between the compared products is sufficiently disclosed.

2. Comparative efficacy

The Challenger argued that the Best in Show commercial conveyed a comparative efficacy message. The Advertiser maintained that the challenged commercial, when viewed in the context of NAD's decision in Bayer Healthcare, LLC (Aleve® Naproxen Sodium Tablets), Report #3915, *NAD/CARU Case Reports* (June 2002) and similar precedent, indicates that no comparative efficacy claim is being made. The Advertiser argued that such precedent established clear rules for effectively comparing the duration of action of products without making an implied efficacy claim including avoiding imagery of subjects in need of relief at the beginning of an advertisement and referencing symptoms or ailments only as a nod to the types of symptoms for which the products are indicated. According to the Advertiser, the challenged commercial follows this formula with the dogs appearing asymptomatic at the beginning of the commercial and the *NexGard*-treated dog scratching being an isolated reference to confirmation of the product category and not a comparative efficacy message. The Advertiser maintained that any reference to product efficacy is so remote that when the *NexGard*-treated dog is shown at the end of the commercial, it is shown without any symptoms.

NAD disagreed. The commercials at issue in Bayer Healthcare, LLC (Aleve® Naproxen Sodium Tablets) differ from the challenged commercial in several material respects. Those commercials included clear indications that limited the comparative claim to the dose and duration of Aleve versus Advil such as a voiceover that "Only two Aleve can stop pain all day – that would take twice as many Advil" and a close up of two hands, one holding two Aleve capsules and another holding four Advil capsules. Thus, NAD determined that the commercials properly limited the comparative claim to the dose and

¹⁵ SPD Swill Precision Diagnostics GMBH (Clearblue Easy Digital Home Pregnancy Test), Report # 5283 NAD Case Reports (January 2011); see also Sanofi-Aventis, Sanofi-Aventis U.S. and Chattem, Inc. (Allegra), Report # 5384 NAD Case Reports (October 2011).

¹⁶ SPD Swiss Precision at 18, citing Novartis Consumer Health, Inc. (Lamisil AT Gel Advanced), Report #4796 NAD Case Reports (February 2008).

¹⁷ NAD also noted that this disclosure appears in the beginning of the commercial but no longer appears on screen when the *NexGard*-treated dog is shown scratching.

duration of Aleve versus Advil. NAD specifically noted that “[t]he voiceover, coupled with the disclosure ‘based on minimum label dosing’ and the two hands holding two Aleve and four Advil can reasonably be interpreted as that both Advil and Aleve can stop pain all day but that the effects of Aleve last longer, a claim that is supported by the products’ FDA-approved labels.” NAD further determined that “[i]n every other regard the commercials are monadic... without any other reference to another product that Aleve helps them bowl, play basketball, go to work or experience relief from minor pain.”

In contrast, the Best in Show commercial contains no voiceover comparing the dosing differences of *Bravecto* and *NexGard*, and the commercial is expressly comparative, not monadic, showing a side-by-side comparison of the two products. Further, far from being an isolated reference, the commercial’s depiction of the *NexGard*-treated dog vigorously scratching is shown for several seconds. The commercial cuts away from a side-by-side comparison to a full screen shot of the *NexGard*-treated dog vigorously scratching while the *NexGard* packaging appears prominently on screen. In addition, once the *NexGard*-treated dog is shown scratching, the only other time the *NexGard*-treated dog is shown is at the end of the commercial when it covers its eyes with its paw in apparent disappointment. NAD determined that one reasonable takeaway from the commercial’s depiction of the *NexGard*-treated dog scratching from flea bites (while the *Bravecto*-treated dog happily wags its tail) is that *Bravecto* is more effective than *NexGard* at protecting dogs from fleas and not merely that *Bravecto* is dosed for 12 weeks as compared to 30 days for *NexGard*. As the Advertiser did not submit evidence that *Bravecto* provides superior protection than *NexGard*, NAD recommended that the Best in Show commercial be discontinued. NAD noted that nothing in this decision prevents the Advertiser from describing that one dose of *Bravecto* will protect a dog from fleas longer than one dose of *NexGard*.

IV. Conclusion

NAD recommended that the Advertiser discontinue the Best in Show commercial and take steps to ensure that when making an “apples-to-oranges” comparison between *Bravecto* and *NexGard*, that the material dosing difference between the compared products is sufficiently disclosed.

V. Advertiser’s Statement

Merck Animal Health will appeal the NAD’s decision to the NARB. Merck respectfully disagrees with NAD’s conclusion that any reasonable consumer could understand Merck’s *Bravecto* commercial to communicate a product distinction other than that one dose of *Bravecto* lasts nearly 3x longer for flea protection than one dose of *NexGard*. NAD disregards the numerous indicia that the commercial is comparing the duration of one dose of *Bravecto* to one dose of *NexGard*. NAD also ignores that the depiction of *NexGard* failing to provide adequate flea protection after 35 days is supported by FDA’s approved indications for the product and Boehringer Ingelheim’s own statements that *NexGard* “works for a month, after which your dog is vulnerable to flea infestations again.” For this reason, Merck Animal Health will appeal NAD’s ruling that the commercial compares *Bravecto* and *NexGard* on any point other than their relative duration of action. (**#7029 HJS, closed 01/20/2022**)