October 28, 2013

Via Electronic Mail

Dirksen Senate Office Building
Washington, D.C. 20510-6125

Dear Senators Durbin, Rockefeller, Blumenthal and Markey,

Rockstar, Inc. ("Rockstar") replies here to your letter of September 25, 2013, requesting a response by October 14, 2013. Your offices previously provided Rockstar an extension until October 28, 2013 to respond to your letter.

Your letter refers to the July 31, 2013 hearing before the Senate Commerce, Science, and Transportation Committee ("Committee"). Although a Rockstar representative attended and testified at the hearing to provide additional information to the Committee regarding Rockstar's proud history and its products, Rockstar appreciates this opportunity to clarify and confirm its formal responses to the questions posed in your letter, having now had an adequate opportunity to study and consider these inquiries.

As a foundational matter, your letter asserts that there are "serious concerns about the potential risks associated with the consumption of energy drink products by children and teenagers." However, the peer-reviewed scientific data regarding caffeine consumption among children and teenagers does not support this position. Rockstar refers to its July 11, 2013 letter to Senator Rockefeller, including its Appendix 1, which is a paper from Dr. Ashley Roberts at Intertek Cantox, clarifying and correcting certain incomplete or inaccurate third-party information previously relied upon by the Committee regarding energy drinks.

As Rockstar's C.F.O. and C.O.O. testified before the Committee, "Rockstar's commitment to consumer safety is the company's number one priority." The use and amount of caffeine contained within Rockstar's energy drinks have been determined, based upon the consensus of a highly qualified expert panel, to be Generally Recognized as Safe ("GRAS") under FDA standards. As part of this determination, the expert panel specifically considered the effect of caffeine on children, and concluded that there is no evidence to support the conclusion that children display increased sensitivities to dietary caffeine.[1] Moreover, the expert panel concluded that under the conditions of intended use of Rockstar's beverages, the combination of all ingredients as used in Rockstar is safe for consumption and GRAS based on scientific procedures.[2]

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[1] The GRAS panel was comprised of the following individuals: Dr. John Doull Ph.D., M.D. (University of Kansas Medical Center); Dr. Stanley M. Tarka Ph.D. (Consultant); and Dr. John A. Thomas Ph.D. (University of Indiana School of Medicine).

[2] Intertek Cantox, Scientific White Paper: Summary of Data Supporting the Safety of Rockstar Energy Drinks 3, 21-23 (April 25, 2013).

As Rockstar's representative noted in her Statement to the Committee, Rockstar has been extremely distressed by the proliferation and amount of inaccurate information that has appeared in the media based upon erroneous reports and manipulated data, including the reports prepared by the Drug Abuse Warning Network ("DAWN"). A careful analysis of the DAWN report and the public data relied upon by the authors does not support the finding of substantial medical harm arising from energy drinks. Attached as Addendum A is an extract from a recent analysis by Pinney Associates, revealing the material flaws in the conclusions asserted by the DAWN report.

With the foregoing in mind, Rockstar's response to your inquiries are noted below. Please note that all of Rockstar's responses pertain to its marketing activity solely within the United States of America, only to those marketing activities which are under Rockstar's control, and as noted herein, are subject to reciprocal compliance by other major energy drink manufacturers.

1. **Will your company agree not to market your energy drink products to (a) children, defined in the ABA's Guidance for the Responsible Labeling and Marketing of Energy Drinks as individuals under the age of 12 or (b) children or minors, under the age of 18? If so, on what date will that commitment take effect?**

   Rockstar does not target the marketing of its energy drink products to children under the age of 12 ("Children"). Rockstar commits to continuing this marketing practice.

2. **Will your company agree that in the future, you will not promote, encourage, or condone rapid or excessive consumption of energy drink products? If so, on what date will that change take effect?**

   Rockstar does not promote, encourage, or condone rapid or excessive consumption of its energy drink products. Rockstar commits to continuing this marketing practice.

3. **Will your company commit to removing any past social media posts or other promotional messages or images that promote, encourage, or condone excessive or rapid consumption of your energy drink products, and, if so, by what date? Will your company commit to regularly monitoring your social media sites to ensure that in the future such messages and images are not posted?**

   Rockstar commits to removing any social media posts or other promotional messages or images (under Rockstar's control) that promote, encourage, or condone excessive or rapid consumption of its energy drink products. Rockstar will commit to

commercially reasonable steps to regularly monitor social media sites under Rockstar's control to ensure that this policy is carried forward into the future.

4. **Will your company agree that in all future marketing and promotional messages, you will not use language implying that consumption of larger volumes of energy drinks or energy drinks with higher concentration of caffeine produces a more desirable effect? If so, on what date will that commitment take effect?**

   Rockstar's energy drinks are marketed in various sizes, including but not limited to 8.4 ounce, 15 ounce, 16 ounce, and 24 ounce containers[3], with concentrations of caffeine at either 10 milligrams or 15 milligrams an ounce. Every Rockstar energy drink, regardless of container size or caffeine concentration, has been determined, based upon the consensus of a highly qualified expert panel, to be Generally Recognized as Safe under FDA standards. Rockstar will continue to truthfully market and promote its products, and it agrees to not make any false or misleading statements regarding the benefits of larger containers of its products, or increased caffeine concentration of its products.

5. **Will your company agree to not promote, encourage, or condone mixing energy drinks with alcohol? Similarly, will your company agree to not make any claim that the consumption of alcohol together with an energy drink counteracts or otherwise positively impacts the effect of alcohol consumption? If so, on what date will that commitment take effect?**

   Rockstar's labels, in addition to Rockstar's website and social media internet sites under Rockstar's control, do not and will not promote, encourage, or condone mixing energy drinks with alcohol. Rockstar further agrees that it does not and will not make any claim that the consumption of alcohol, together with an energy drink, counteracts or otherwise positively impacts the effect of alcohol consumption.

6. **Will your company agree to not promote, encourage, or condone the mixing of energy drinks with sleeping pills or other drugs? Similarly, will your company agree to not make any claim that the consumption of an energy drink in any way counteracts or otherwise positively impacts the effect of sleeping pulls or other drugs? If so, on what date will that commitment take effect?**

   At the July 31, 2013 hearing before the Committee, Rockstar observed the Red Bull advertisement which it understands to be the genesis of this question. Unlike Red Bull, Rockstar does not promote, encourage, or condone the mixing of energy drinks

[3] All of Rockstar's 24-ounce products come only in re-sealable cans.

with sleeping pills or other drugs, nor has it made any claim that the consumption of an energy drink in any way counteracts or otherwise positively impacts the effect of sleeping pills or other drugs. Rockstar agrees to not make any such claims in the future.

7. **Will your company agree not to market your energy drink products in K-12 schools, including at any school-related events or activities? If so, on what date will that commitment take effect?**

   Rockstar does not market its energy drinks in K-12 schools, including at any school-related events or activities in such schools, and it agrees to continue this practice.

8. **Will your company ensure that its energy drink products are not sold in K-12 schools, including in automated vending machines and concession stands? If so, on what date will that change take effect?**

   Rockstar does not sell any of its energy drink products in K-12 schools, including in automated vending machines and concession stands located on the grounds of K-12 schools. Rockstar agrees to continue this practice.

9. **Will your company agree to not provide samples of your energy drink products in or within the immediate vicinity of K-12 schools? If so, on what date will that change take effect?**

   Rockstar does not provide samples of its energy drink products in or within the immediate vicinity of K-12 schools, and it agrees to continue this practice.

10. **Will your company include binding contractual language in future contracts with distributors, promoters, or other third party entities prohibiting them from marketing, promoting, selling, or sampling to children and teenagers in K-12 schools? If so, on what date such language be inserted into new contracts?**

    Rockstar agrees to make commercially reasonable efforts to include contractual language in future contracts with its distributors instructing that the latter not market, promote, sell or sample in K-12 schools.

11. **Will your company commit to including on the product label of your energy drinks a clear declaration of the total amount of caffeine present by serving and per container, and, if so, by what date will those labels be included?**

    Unlike many of its competitors, Rockstar has long declared in a clear manner on its

labels the total amount of caffeine present from all sources by serving and per container. Rockstar has voluntarily disclosed this information on its products since at least 2006. Rockstar agrees to continue this practice.[4]

12. Will your company commit to voluntarily report to the FDA any serious adverse events associated with the consumption of your energy drink products of which you become aware? If so, on what date will that commitment take effect?

Rockstar agrees to voluntarily report to the FDA, in a manner consistent with the serious adverse event reporting requirements applicable to dietary supplements pursuant to the Dietary Supplement and Nonprescription Drug Consumer Protection Act, any serious adverse events associated with the actual consumption of its energy drinks of which it becomes aware. Rockstar will begin this practice no later than January 1, 2014.

13. Will your company commit to putting restrictions in place for any social media sites owned, managed, or operated by your energy drink product lines or managers that would restrict access for users under the age of 18, if such social media site has the capability to impose age restrictions? If not, is there an age under 18 for which you would commit to such restrictions? If so, what age and on what date would the restriction take effect?

Rockstar understands that Facebook "requires everyone to be at least 13 years old before they can create an account."[5] Similarly, Instagram does not allow anyone under the age of 13 to register for its services.[6] Rockstar's own website states that it "is not designed or intended for children under the age of 13" and those under the age of 13 are not permitted to register on the Rockstar site. As noted in response to Question 1, Rockstar does not target the marketing of its energy drink products to children under the age of 12 ("Children"). Rockstar commits to continuing these practices regarding its website and other online marketing.

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[4] The April 10, 2013 report authored by the staff of (then) Congressman Edward J. Markey, written in coordination with the staff of Senators Richard J. Durbin and Richard Blumenthal, entitled *What's All the Buzz About?*, incorrectly states that Rockstar is "transitioning to labeling caffeine on all products." Table 3, p. 12. As noted above, Rockstar has provided the total amount of caffeine from all sources, per serving and per container, on its labels in a transparent manner for at least the past seven years.

[5] https://www.facebook.com/help/441374602560317/

[6] http://instagram.com/legal/privacy/#section6

14. **Will your company restrict any advertising buys or purchases for TV, radio, print, internet, or mobile devices and directly target audiences that are more than 35% under the age of 18, and, if so, by what date will this restriction be adopted?**

    Rockstar agrees to restrict any advertising buys or purchases for television, radio, print, and internet where it is aware through validated third-party data that such buy would directly target an audience which is predominantly comprised of Children (those under the age of 12). Rockstar believes that this practice is already in effect, but will ensure that is in compliance with this request by January 1, 2014.

15. **Will your company agree to label any of your products that include caffeine in excess of the FDA's approved GRAS standard for caffeine in cola with either of the following statements:**

    "This product is not intended for individuals under the age of 18 years of age, pregnant or nursing women, or for those sensitive to caffeine"

    If you will agree to include either statement on your energy drink product(s), by what date will such statement be included?

    Rockstar reiterates that all of its energy drinks have been determined, based upon their intended use and the consensus of a highly qualified expert panel, to be GRAS under FDA standards. In addition, the expert panel specifically considered the effect of caffeine on children, and concluded that there is no evidence to support the conclusion that children display increased sensitivities to dietary caffeine.

    Notwithstanding the above, since at least as early as 2004, Rockstar has voluntarily placed the following declaration on all of its labels:

    "NOT RECOMMENDED FOR CHILDREN, PREGNANT OR NURSING WOMEN, OR THOSE SENSITIVE TO CAFFEINE"

    Rockstar agrees to continue with this longstanding practice.

16. **Will your company commit to not feature, recruit, or sponsor children under the age of 18 in energy drink marketing campaigns, including promotion on social media? If not, is there an age under 18 for which you would commit to not feature, recruit, or sponsor in energy drink marketing campaigns? If so, what age and on what date will such commitment take effect?**

    Rockstar commits to not recruit Children (those whom Rockstar is aware are under the age of 12) in energy drink marketing campaigns. Furthermore, Rockstar will not feature such individuals consuming or promoting its energy drinks, or images

featuring persons where those pictured are predominantly Children (as defined above), on marketing, including social media, which Rockstar manages or otherwise controls. Rockstar also will not sponsor or promote Children (as defined above), nor will it sponsor or promote events and/or activities that are intended for an audience predominantly comprised of such individuals. Rockstar believes that this practice is already in effect, but will ensure that is in compliance with this request by January 1, 2014.

17. **The National Collegiate Athletic Association and the National Federation of State High School Associations has advised student athletes to avoid energy drinks and other stimulants because they may be detrimental and are not effective forms of fuel or hydration. The American Beverage Association has drawn a functional difference between energy drinks and sports drinks. Does your company commit to not market its energy drinks as sports drinks or in a manner that could confuse its energy drink products with that of a typical sports drink, which contains electrolytes and other ingredients intending to hydrate the body, and if so by what date will that commitment take effect?**

The term "sports drink" is not defined by the FDA, and the distinction between sports drinks and energy drinks is not an FDA distinction. This distinction was adopted years prior by American Beverage Association ("ABA") industry members before Rockstar (and Monster) agreed to join the ABA. As a condition to Rockstar joining the ABA, the latter agreed that it would change this outdated language. Rockstar would not have joined the ABA without the ABA's advance agreement to change these guidelines, given the industry innovation and products like Rockstar Recovery.

Moreover, this question is based on the premise that the ingestion of caffeine from an energy drink causes a diuretic effect, resulting in detrimental athletic performance, and the premise that energy drinks do not contain electrolytes and other ingredients similar to traditional sports drinks, which are intended to hydrate the body. As shown below, both of these premises are incorrect.

In a paper written by Dr. Lawrence L. Spriet and Dr. Terry E. Graham, both Fellows of the American College of Sports Medicine,[7] the two noted that "the available literature does not support immediate diuretic effect" with respect to caffeine ingestion "as body core temperature, sweat loss, plasma volume and urine volume were unchanged" in studies following caffeine ingestion. To the contrary, the pair wrote that the applicable research "suggests that caffeine ingestion improves

[7] The American College of Sports Medicine, the largest sports medicine and exercise science organization in the world with more than 45,000 members and certified professionals worldwide, asserts that it is dedicated to advancing and integrating scientific research to provide educational and practical applications of exercise science and sports medicine. See www.acsm.org.

performance during short-term exercise."[8] In other words, the applicable research supports the position that the ingestion of caffeine, such as an energy drink, prior to exercise improves athletic performance.

More importantly, certain energy drinks, such as Rockstar Recovery and Monster Rehab, do contain electrolytes and other ingredients intended to hydrate the body. These products have come on the market only in the last few years, subsequent to the ABA guidelines referenced in the question above. When Rockstar became a member of the ABA, the ABA acknowledged that the provision at issue did not apply to Rockstar Recovery and similar energy products, such as Monster Rehab, which also offered hydration benefits due to such ingredients as electrolytes.

A standard sixteen ounce can of Rockstar Recovery contains not only 160 milligrams of caffeine, but also 220 milligrams of sodium and 80 milligrams of potassium amongst its ingredients. As shown in the paper authored by Dr. Ashley Roberts at Intertek Cantox, entitled *Hydration Statement on Rockstar Recovery Energy Drinks* (attached hereto as Addendum B,) "the available published empirical data, along with the current state of knowledge with respect to physiological processes related to hydration and water absorption," support the view that Rockstar Recovery offers hydration benefits, notwithstanding its caffeine content.

Rockstar and Monster, who represent over 50% of the volume of energy drinks sold in the United States, are currently working with the ABA in good faith to develop Model Energy Drink Guidelines (the "Proposed Model Guidelines") (attached hereto as Addendum C). The Proposed Model Guidelines go far beyond those offered by others in the beverage industry who produce caffeinated beverages, such as Starbucks, which delivers more than twice as much caffeine to consumers in a cup of coffee as compared to the same size serving of a standard energy drink (a sixteen ounce drip coffee of Starbucks Pike Place Roast contains **330 mg** of caffeine compared to **160 mg** of caffeine in a sixteen ounce can of Rockstar Recovery).[9]

As noted in the Proposed Model Guidelines, Rockstar reserves the right to revisit any portion of the Proposed Model Guidelines to the extent required by applicable law or changes in economic and/or competitive conditions affecting the energy drink

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[8] See Lawrence L. Spriet, Ph.D. and Terry E. Graham, Ph.D., *Caffeine and Exercise Performance*, ACSM Current Comment, http://www.acsm.org/docs/current-comments/caffeineandexercise.pdf.

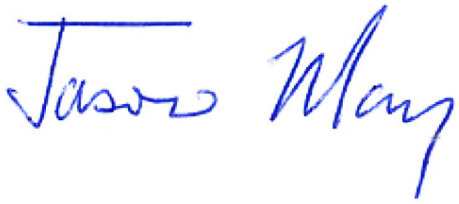
[9] It is estimated that Starbucks is also the fifth largest seller of energy drinks in the United States, based largely on its Doubleshot and Refreshers products. Although it does not appear that Starbucks has been asked by the Senators to voluntarily commit to undertake certain marketing practices regarding its own energy drinks (for reasons which are very unclear to Rockstar), Starbucks' agreement to the Proposed Model Guidelines would certainly strengthen their effectiveness and breadth, given the massive volume of energy drinks that Starbucks sells every year in the United States.

segment, including non-compliance with the Proposed Model Guidelines by major energy drink companies. For example, if Red Bull, either itself or through a subsidiary or third party, directly or indirectly continues its longstanding practice of sponsoring and/or compensating child athletes (those 12 and under), then Rockstar reserves the right to reconsider its commitments herein on that topic.[10] This demonstrates the need for Red Bull, Starbucks, and other major energy drink sellers to agree to the Proposed Model Guidelines to ensure fairness and a level playing field for all concerned.

Rockstar appreciates the opportunity to present its formal response to these inquiries after its careful consideration of these issues. It hopes that its responses, along with the supplied Proposed Model Guidelines, documented scientific research, and other voluntary measures which Rockstar has long had in place, convey just how seriously Rockstar takes the safety of its products.

Please feel free to contact me anytime if you have any questions or require any additional information.

Best Regards,



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[10] To the best of Rockstar's knowledge, to date Red Bull has refused to agree that it, and its subsidiaries/affiliates, will cease sponsorship and/or endorsement of child athletes aged 12 and under.

ADDENDUM A:

Review of DAWN Report Data

Prepared by PINNEY ASSOCIATES

1) Conclusion:

Although the DAWN report has attracted a lot of attention, careful analysis of the report and the public data underlying it, do not appear to be consistent with a signal of substantial medical harm The vast majority of caffeine/multivitamin-related ED visits appear to be associated with non-serious complaints that do not require further medical follow-up, as 84.4% of visits related to these products resulted in discharge home, a higher rate than observed for other products. The reported rate of ED visits related to caffeine/multivitamins remains quite small, representing a tiny fraction of the overall visits to EDs each year. Finally, the limitations of the DAWN system suggest caution in basing public health policy on the results relative to energy drinks. It is important to understand that DAWN's reporting is not based on a straightforward enumeration of cases. DAWN projects to a national estimate of cases based on combining results from two sources: approximately 183 hospitals in 13 major metropolitan areas, and approximately 50 supplementary hospitals in 2011. Although the metropolitan hospitals actually report more cases, the supplementary hospitals actually exert greater influence on the projected national estimate. On average, one case in the supplementary sample represents 135 weighted cases, whereas one case in any of the 13 main metropolitan areas represents, on average, fewer than 5 weighted cases (see Appendix Table 4). Therefore, a single case from a supplementary hospital can count 27 times more than a case from one of the metropolitan hospitals that report data to DAWN. This can distort the estimate. For example, a small 'outbreak' at a community hospital could potentially skew the national statistics; a single case of energy drink use presenting to a hospital in the supplementary sample could be counted as though it were 863 cases (the maximum weight for a single case in 2011), possibly seriously skewing the national statistics and resulting in misleading trend data.

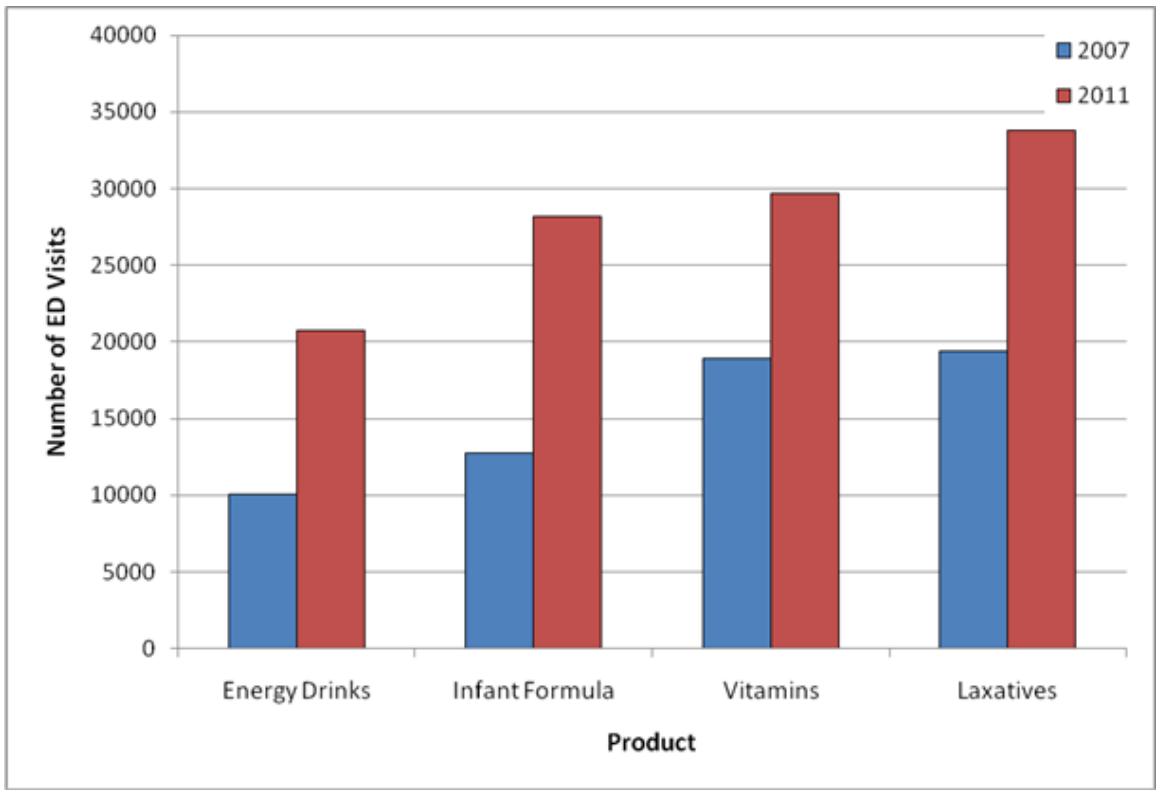
In 2011, the vast majority (85.6%) of weighted caffeine/multivitamin-related ED visits were derived from the supplementary sample. This does not appear to be unique to caffeine/multivitamins, however, as an analysis of selected comparator products (i.e., nutritional products, alternative medicines, and CNS stimulants) revealed that for these three other drug classes/product categories the bulk of the weighted reporting is also coming from the supplementary sample: 83.7% for nutritional products, 83.4% for alternative medicines, and 87.3% for CNS stimulants.

2) Increasing Number of Energy Drink-Related ED Visits: Real Phenomenon or Artifact?

According to the SAMHSA report, the number of ED visits involving energy drinks doubled from 10,068 visits in 2007 to 20,783 visits in 2011.[1] Notably, however, an analysis of DAWN public-use data indicates that the total number of overall drug-related ED visits (regardless of the specific drug/s involved) also increased between 2007 and 2011, rising from 3.9 million visits to 5.1 million visits. Therefore, the increase in energy drink-related visits should be understood in the context of an increase in overall drug-related ED visits. It is not known whether this reflects a real increase in the utilization of EDs, or an artifact perhaps resulting from change in the data collection or case identification methodology. In 2007, energy drink-related visits comprised 0.25% of all drug-related ED visits. In 2011, energy drink-related visits comprised 0.41% of all drug-related ED visits.

Furthermore, as shown in Table 1 below, estimated drug-related ED visits appear to have increased not only for energy drinks, but for a number of other drugs/products, including infant formula, alternative medications, and other miscellaneous products such as dermatological agents (e.g., Vick's, hand lotion), gastrointestinal agents (e.g., laxatives), isopropyl (rubbing) alcohol, and ophthalmic preparations (e.g., eye drops, contact solution). Not only have drug-related ED visits increased for these other products by similar proportions as for energy drinks, for many, their absolute magnitude is similar, too (see Figure 1 below). In addition, energy drink-related ED visits appear to be more likely to be associated with non-serious complaints that do not require further medical follow-up, compared to ED visits related to other product/medications. Yet, increasing ED visits associated with these other products have not been identified as a public health concern.

Figure 1 Number of ED Visits Related to Specific Products:



It is unclear whether these data reflect an increase in the levels of accidental and/or intentional exposure to substances and drugs in general, including energy drinks, or if there are methodological and statistical processes that may give the appearance of notable increases in drug-related ED visits. It is possible, for example, that the observed increases in some categories could be due to increased awareness by health professionals of certain substances, or increased perception of certain categories as problematic. This could lead to either increased detection of such substances (e.g., if the medical interviewer asks about them more than previously) or increased attribution of ED visits to the substance (e.g., if the medical interviewer is more likely to record the substance or to name it as a factor in the ED visit).

Table 1 Number of ED Visits Related to Specific Products

Drug	2007	2008	2009	2010	2011	% Change, 2007-2011
Total drug-related ED visits	**3,998,228**	**4,383,494**	**4,595,263**	**4,916,328**	**5,067,374**	26.74%
Total drug reports	**6,248,023**	**6,957,634**	**7,270,914**	**7,808,492**	**8,046,258**	28.78%
Caffeine/multivitamin	12,750	18,970	14,415	18,734	29,379	130.42%
Energy drinks	*10,068*	*16,059*	*13,119*	*15,219*	*20,783*	*106.43%*
Nutritional products	59,389	74,437	80,724	93,749	95,089	60.11%
Iron products	7,800	8,885	11,020	12,982	12,711	62.96%
Minerals and electrolytes	11,140	16,364	15,088	16,094	14,946	34.17%
Electrolyte replacement solutions, oral[a]	673	689	855	1,282	1,824	171.03%
Oral nutritional supplements	15,388	15,919	20,835	26,014	33,855	120.01%
Infant formula	12,764	12,019	16,582	22,242	28,212	121.03%
Vitamin and mineral combinations	9,499	13,566	13,847	16,369	14,834	56.16%
Vitamins	18,915	26,905	28,857	29,381	29,672	56.87%
Alternative medicines	13,320	15,892	15,951	20,806	24,222	81.85%
Herbal products	8,603	6,661	8,864	11,915	12,508	45.39%
Nutraceutical products	4,385	8,975	7,356	8,600	10,087	130.03%
Probiotics	330	485	128	752	1,760	433.33%
Gastrointestinal agents	78,826	94,468	104,390	101,940	103,358	31.12%
Antidiarrheals	6,947	8,462	8,526	12,113	10,859	56.31%
Laxatives	19,424	28,053	27,621	29,668	33,861	74.33%
Dermatological agents	30,072	30,438	36,016	44,262	50,632	68.37%
Topical emollients	2,832	2,937	2,972	5,622	4,836	70.76%
Hydrocortisone, topical	2,019	2,817	4,206	4,284	3,997	97.97%
Camphor[b]	460	1,402	238	1,032	2,204	379.13%
Hydrogen peroxide, topical	593	471	957	2,361	1,503	153.46%
Miscellaneous						
CNS Stimulants	48,732	53,169	53,652	66,888	93,457	91.78%
Caffeine[c]	6,434	5,930	7,293	8,633	8,936	38.89%
Isopropyl alcohol, topical	2,252	4,504	2,473	2,779	3,219	42.94%
Ophthalmic preparations[d]	9,137	9,125	11,828	13,653	14,506	58.76%

[a] Electrolyte replacement solutions include products such as Gatorade, Powerade, Pedialyte, etc.

[b] Camphor includes products such as Vick's, Biofreeze, etc.

[c] Caffeine includes coffee, as well as other caffeine-containing products.

[d] Ophthalmic preparations include contact solution, eye drops, etc.

Of the overall caffeine/multivitamin-related ED visits in 2011, 84.4% resulted in discharge home. Considering ED visits related to caffeine/multivitamin use only (i.e., no other drug involvement), the percentage of visits resulting in discharge without any further follow-up was even higher (88.3%), demonstrating that the vast majority of energy drink-related ED visits are for non-serious complaints that do not require further medical care. Notably, home discharge rates for caffeine/multivitamin-related ED visits are substantially higher than those for drug-related ED visits overall (63.8%). These findings are consistent with information from the American Association of Poison Control Centers' (AAPCC) National Poison Data System which indicates that in cases involving energy drink exposure where medical outcome was assessed, the vast majority of cases were considered to be not serious (83% of cases with medical outcomes classified as "none" or "minor").[2] This suggests that ED visits associated with consumption of energy drinks are not as serious as those associated with other drugs.

Table 2 Home discharge rates for selected ED visit types:

Visit Type	% of Visits Resulting in Discharge Home
All drug-related ED visits	63.8%
Caffeine/multivitamin-related visits	84.4%
Nutritional products-related visits	80.3%
Alternative medicines-related visits	75.5%
CNS stimulants-related visits	74.2%

ADDENDUM B:

Hydration Statement on Rockstar Recovery Energy Drinks

Prepared by INTERTEK

Hydration Statement on Rockstar Recovery Energy Drinks

Introduction

Intertek Cantox has been asked to evaluate whether there is adequate substantiation (*i.e.,* a reasonable basis) for the use of the terms “hydration” and “electrolytes” in the labeling and advertising of Rockstar’s Recovery Energy Drinks. For health-related claims (*e.g.,* related to hydration), the Federal Trade Commission (FTC) has required “competent and reliable scientific evidence”, defined as *tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results*.

Thus, in the current report, the scientific evidence that corroborates that use of the terms “hydration” and “electrolytes” in the labeling and advertising of Rockstar’s Recovery Energy Drinks is surveyed.

Composition of Rockstar’s Recovery Energy Drinks

Based on the labels provided to Intertek Cantox, those products that have associated electrolyte and hydration claims contain the following ingredients per 16 oz can: sodium (220 mg), potassium (80 mg), carbohydrates as sugars (6 g), taurine (2,000 mg), and caffeine (160 mg). Rockstar’s Recovery Energy Drinks also includes other minor ingredients as shown on the label below in Figure 1.

Figure 1 Label of Rockstar's Recovery Energy Drinks

The Physiology of Hydration

In adult humans, water accounts for about 60% of body weight (ILSI, 2004; Hall, 2011). This figure is higher in infants (80%) and lower in the elderly (typically about 45 to 55%) (IOM, 2004; Hall, 2011). In the body, about 2//3 of the water is intracellular, or inside individual cells. The remainder is called extracellular and lies outside of cells, either within blood vessels (*i.e.*, intravascular), between cells (*i.e.*, transcellular) such as in the case of cerebrospinal, pericardial and synovial fluid), or between blood vessels and cells (*i.e.*, interstitial) (ILSI, 2004, IOM, 2004; Hall, 2011).

The maintenance of body water homeostasis requires that the loss of water and electrolytes must precisely match intake. The process that governs water homeostasis is osmoregulation

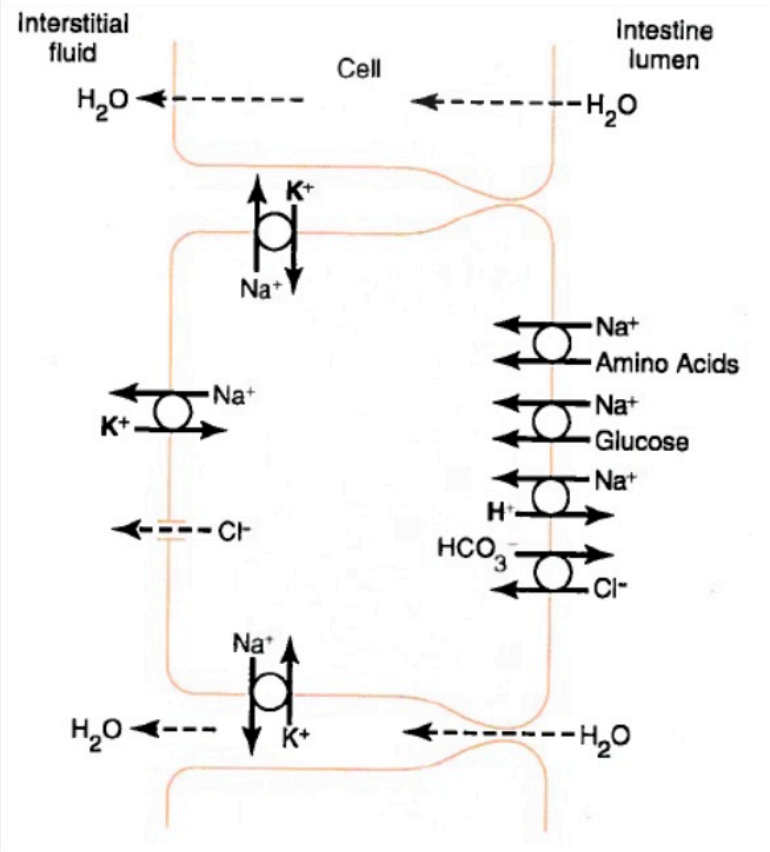
(IOM, 2004). Water excretion is controlled by the anti-diuretic hormone (also known as arginine vasopressin) (Cheng et al., 2009), a hormone that is secreted by the posterior pituitary. This hormone promotes the re-absorption of water by the kidneys (O'Neill and McLean, 1992). The secretion of anti-diuretic hormone is stimulated by signals from the hypothalamus sent in response to the activation of osmoreceptors (O'Neill and McLean, 1992). Osmoreceptors in the brain respond to the plasma osmolality, which is a measure of the concentration of solutes in the blood. Normally, the plasma osmolality is in the range of 200 to 330 mOsmol/kg blood (O'Neill and McLean, 1992; IOM, 2004; Hall, 2011). When the plasma osmolality is above a certain threshold (*i.e.*, when the plasma is dilute or water is in excess), the secretion of anti-diuretic hormone is inhibited leading to greater water loss in the urine. The desire to drink fluids, or thirst, occurs when the plasma osmolality increases to the point that suppression of anti-diuretic hormone alone may be insufficient to maintain fluid balance (Phillips et al., 1984; O'Neill and McLean, 1992; Cheng et al., 2009; Kolasa et al., 2009; Millard-Stafford et al., 2012). Beyond water intake, hydration status, as measured by plasma osmolality, is affected by many factors, including age, weight, percent body fat, level of physical activity, environmental temperature and humidity, nature and amount of sweat produced, among others (IOM, 2004; ILSI, 2004).

The intake of water can be highly variable depending upon the thirst response and availability of fluids. To maintain hydration (*i.e.*, water homeostasis), it has been recommended that the average adult human consume from 2.0 (EFSA, 2010) to 3.7 L of water per day (IOM, 2004; ILSI, 2004; Campbell, 2007). Insufficient fluid intake can result in dehydration, signs of which include little or no urine, dark yellow-brown urine, dry mouth and skin, headache confusion, light-headedness, and reduced tear production (IOM, 2004). With respect to "hydration" and other related claims, it is of note that several regulatory bodies and/or authoritative reviews have essentially concluded that water, and beverages that contain water, including those containing caffeine (IOM, 2004; ILSI, 2004, 2007; EFSA, 2010), and or carbohydrate-electrolyte combinations (EFSA, 2011), can be considered as hydrating and/or to be without adverse effect on measures of hydration (Rodriquez et al., 2009; Goldstein et al., 2010; Campbell et al., 2013).

Ingested water, either in the form of water *per se*, or as water-containing beverages, is rapidly absorbed from the small intestine (Hall, 2011). Water is transported through the intestinal membrane entirely through diffusion (Wright and Loo, 2000). Diffusion follows the basic laws of osmosis. Osmosis is the net movement of water across a selectively permeable membrane driven by a difference in solute concentrations on the two sides of the membrane (Hall, 2011; Colorado State University, 2013). A selectively permeable membrane is one that allows unrestricted passage of water, but not solute molecules or ions. In other words, water is drawn across a semi-permeable membrane from a solution that is dilute with respect to solute concentration and into a solution that is "concentrated" with solutes (Hall, 2011; Colorado State University, 2013). It is for this reason that water absorption in the small intestine, and hence

hydration, is coupled with the absorption of solutes (electrolytes), most notably sodium (Love et al., 1968; Leiper, 1998; Hall, 2011; Colorado State University, 2013). Briefly, sodium that is absorbed from the intestinal lumen into enterocytes (cells on the absorptive surface of the intestinal villi) is rapidly pumped out of the cell into the intercellular spaces (Leiper, 1998; Wright and Loo, 2000; Hall, 2011; Colorado State University, 2013). This creates a high concentration of sodium in the paracellular space leading to the establishment of an osmolality gradient that then draws water by osmosis from the intestinal lumen into the intracellular space, and subsequently into capillary blood within the intestinal villus (Leiper, 1998; Hall, 2011; Colorado State University, 2013). The presence of sodium and other electrolytes that co-transport with sodium, allows for water absorption even when the chyme is slightly hypertonic with respect to the blood (Leiper, 1998; Wright and Loo, 2000). Sodium is therefore the key electrolyte involved in water absorption and therefore hydration. A diagrammatic representation of the absorption of water by the intestinal villi is shown in Figure 1.

Figure 1 Diagrammatic representation of osmotic water flow from the lumen of the intestine to the interstitial fluid



Source: Hall (2011)

An adequate supply of sodium assuming that co-transport substances such as glucose and amino acids are present, is required to initiate the absorption of sodium into the enterocytes, present within the lumen of the small intestine (Lifshits and Wapnir, 1985; Gisolfi et al., 1992; Leiper, 1998; Wright and Loo, 2000). Ingestion of beverages that contain sodium and other electrolytes, therefore, can provide for an increase in the rate of water absorption relative to consumption of water alone. Proof of this concept has been demonstrated using an *in vivo* perfusion system (rat jejunum) whereby a solution containing 60 mEq/L sodium and 111 mM glucose resulted in the maximal influx of both sodium and water relative to other combinations of water and/or water/solute (Lifshitz and Wapnir, 1985). While Rockstar contains sodium (220 mg per 16 oz can) and carbohydrates at lower levels (6 g/16 oz can) than those used in the Lifshitz and Wapnir (1985) study, inclusion of these solutes, especially sodium, is expected, based on physiological principles, to have a net beneficial effect on water absorption and therefore hydration (Leiper, 1998).

To the extent that a solute containing beverage could promote hydration, at least in relation to consumption of water alone, it is important to consider the osmolality of the beverage involved. The evidence provided by consensus scientific opinions and reports from authoritative bodies shows that glucose-electrolyte solutions with an osmolality which is isotonic or slightly hypotonic with respect to plasma (*i.e*., 200-330 mOsm/kg water) maximise the rate of water uptake, and that the addition of carbohydrates to electrolyte solutions promotes water absorption in the small intestine (Henry et al., 1974; O'Neill and McLean, 1992; Hall, 2011). Solutions that are hypotonic with respect to the blood could be expected to result in faster/greater water absorption relative to those that are hypertonic (*i.e*., promote osmotic diffusion of water from the intestinal lumen through the paracellular spaces between enterocytes into the capillary blood of the villi) (Lifshitz and Wapnir, 1985; Leiper, 1998; Colorado State University, 2013). Infusion of hypertonic solutions into the lumen of the small intestine results in the movement of water from the paracellular space toward the intestinal lumen until the luminal contents are isotonic with the intercellular space and blood. Water that is excreted into the intestinal lumen in response to the presence of hypertonic fluids is eventually reabsorbed in the distal ileum or in the colon (Hall, 2011). As a result, for rapid hydration, consumption of hypotonic beverages is recommended. The osmolality of Rockstar's Recovery Energy Drinks is about ~150 mOsM, thus, from a physiological point of view, it would support hydration upon consumption.

The nature of the solutes present in beverages can potentially affect the manner in which they support hydration. Dilute hypotonic solutions containing glucose/carbohydrates and sodium have been demonstrated to be efficient rehydration solutions (Lifshitz and Wapnir, 1985; Leiper, 1998), and have been recognized as such by the European Food Safety Authority (EFSA, 2011). Addition of other solutes appears not to significantly further potentiate water absorption.

Solutions containing glucose or other carbohydrates at concentrations of greater than 8% can impair gastric emptying and delay water absorption (Gisolfi et al., 1992; Rodriguez et al., 2009). Carbohydrates are present in Rockstar at much lower concentrations, in the order of about 1.2% (*i.e*., 6 g in 0.473 kg of solution) and hence would not exert any type of suppressant effect on water absorption.

In addition to the levels of electrolytes and carbohydrate within the Rockstar beverages the products also contain caffeine. Conventional wisdom held that caffeine has diuretic properties (Grandjean et al., 2000; IOM, 2004). A review of the empirical evidence, however, shows that caffeine in doses of 250 mg/day or more in naive drinkers may induce a mild, but transient, diuretic effect, particularly in subjects who are at rest (Wemple et al., 1997). However, regular caffeine users become habituated to the effects of caffeine, diminishing its actions (Armstrong, 2002; Maughan and Griffin, 2003). Also, studies which have assessed the consumption of caffeine on hydration status, have failed to show any substantive difference to non-caffeinated beverages, including water. Specifically, no studies have found an adverse effect of consumption of caffeine at moderate doses on hydration during or following light to heavy exercise (Falk et al., 1990; Grandjean *et al.*, 2000; Armstrong, 2002; Fiala et al., 2004; Roti *et al.*, 2006; Millard-Stafford et al., 2007; Del Coso et al., 2009; Goldstein *et al.*, 2010; Campbell *et al.*, 2013). The results of the aforementioned studies with caffeine and caffeine containing beverages support the conclusions of recent authoritative reviews of hydration needs which have stated that all beverages hydrate, including those containing caffeine (IOM, 2004; ILSI, 2004, 2007; EFSA, 2010). As noted by EFSA (2010), “only in habitual consumers of high amounts of caffeine (600 mg/day)...., a correction of observed total water intakes for diuretic losses may be advisable in order to ensure that water intake is adequate (Stookey, 1999)”. As Rockstar beverage contains up to 160 mg/16 oz (473 mL) can, and is hypotonic with respect to the blood, it, too, would serve as a source of hydration.

Hydration Claim Substantiation

There is no regulatory definition of the term “hydration”. The use of the term, however, could constitute a structure/function claim (*i.e.,* a claim of an effect on structure or function of the body). As with other claims, a structure/function claim must be adequately substantiated.

Hydration involves the replenishment of body water that is lost through normal metabolic processes, including digestion of food, sweating, breathing, and urination (IOM, 2004). Typically, normal adults are thought to require 2.0 to 3.7 L of water per day. Notably, it is widely recognized that hydration can be obtained from water as well as beverages that contain water, including those that contain caffeine (IOM, 2004; ILSI, 2004, 2007; EFSA, 2010).

The physiological processes involved in water absorption, particularly the sodium-glucose co-transport mechanism that establishes a positive osmotic gradient, require the presence of

sodium to function given an adequate supply of co-transporters (*e.g.*, amino acids and/or glucose) (Love et al., 1968; Lifshitz and Wapnir, 1985; Leiper, 1998; Wright and Loo, 2000; Hall, 2011; Colorado State University, 2013), with sodium being the key electrolyte involved in the process. As such, the inclusion of 220 mg of sodium per 16 oz can (*i.e.*, a concentration of 465 mg/L), as in the Rockstar Recovery Energy Drinks, will promote water absorption or "hydration". Furthermore, the fact that the Rockstar beverage is hypotonic with respect to blood will, therefore, aid and not impede water absorption in the small intestine. While Rockstar beverages making hydration claims contain caffeine (160 mg/16 oz can), this level of caffeine is insufficient to induce a diuretic effect. Moreover, a review of the empirical evidence indicates that while doses of caffeine in excess of 250 mg may have a mild, transient diuretic effect in persons not habituated to caffeine, it does not provide any evidence that moderate consumption of caffeine has any adverse effect on hydration status in healthy adults, either at rest or under conditions of exercise (Falk et al., 1990; Grandjean *et al.*, 2000; Armstrong, 2002; Fiala et al., 2004; Roti *et al.*, 2006; Millard-Stafford et al., 2007; Del Coso et al., 2009; Goldstein *et al.*, 2010; Campbell *et al.*, 2013).

In summary, the available published empirical data, along with the current state of knowledge with respect to physiological processes related to hydration and water absorption, support the hydration label claim on Rockstar's Recovery Energy Drinks. Such a conclusion is mirrored by the position of the American College of Sports Medicine. Researchers from this group (Rodriguez et al., 2009) have stated that: "consumption of beverages containing electrolytes and carbohydrates can help sustain fluid and electrolyte balance...". This statement is further supported by EFSA's Scientific Opinion (EFSA, 2011) on the substantiation of health claims related to carbohydrate-electrolyte drinks. EFSA (2011) concluded, in reference to "enhancement of water absorption", which encompasses such terms as "hydration", "rehydration", "water and electrolyte balance", and "nutrient absorption", that "carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise", essentially validating the claim of "hydration". The Rockstar Recovery Energy Drinks contain the key sodium electrolyte at 465 mg/L, which is in the range of levels that were the subject of the hydration claims assessed by EFSA (2011). In addition the levels of sodium and carbohydrates are consistent with the promotion of hydration from the standpoint of human physiology and, moreover, cannot be found to be excessive in regards to the functioning of processes governing water absorption. Finally, the consideration of Rockstar as a hydrating agent is consistent with the conclusion of the IOM (2001) that all beverages (except those that are hypertonic relative to blood) can be considered hydrating.

The Term "Electrolytes"

The term "electrolytes", on its own is **not** considered to be a health claim or a structure/function claim. Rather, the term "electrolytes", on its own, describes what is in the beverage. While the

Rockstar beverage contains the following electrolytes; sodium, potassium, magnesium and calcium, the amount of electrolytes contained within the product is not being quantified within the claim. Furthermore, there is no clearly defined standard for the levels of electrolytes required to support the use of the term “electrolytes” in food labeling, generally, or for a food product in the “hydration” sector and the term has no legal or regulatory definition. At a minimum, it is anticipated that a product bearing the term “electrolytes” should consist of at least 2 electrolytes (based on the use of the plural “electrolytes”) and as such the fact that the Rockstar beverage contains four electrolytes indicated that the term is truthful and supports the label claim.

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ADDENDUM C:

Proposed Model Energy Drink Guidelines

Proposed U.S. Model Guidelines

The following are commitments that major energy drink manufacturers have agreed to voluntarily adopt regarding the labeling and marketing of their respective energy drinks ("Energy Drink/s"):*

Labeling

- Energy Drink/s will be labelled as conventional foods/beverages, and not as dietary supplements.

- Energy Drink labels will include a clear declaration of the total amount of caffeine (from all sources) in the container, on a per can/bottle basis and, for multi-serving containers, on a per serving basis (e.g., "caffeine content: xx mg/8 fl ox; yy mg/per can."). This quantitative caffeine declaration will be separate and apart from the ingredient statement and the Nutrition Facts Panel.

- Energy Drink labels will include an advisory statement conveying substantially the following: "CONSUME RESPONSIBLY: Not recommended for children, people sensitive to caffeine, pregnant women or women who are nursing."

- Energy Drink labels will not promote or encourage mixing Energy Drink/s with alcohol nor make any claims that the consumption of alcohol together with Energy Drink/s counteracts the effects of alcohol.

- Energy Drink labels will not promote or encourage excessive or unduly rapid consumption of Energy Drink/s.

Marketing

- Energy drink manufacturers will not target their marketing of Energy Drink/s to children under 12 years of age ("Children") as defined in the International Council of Beverages Association's (ICBA) Global Policy on Marketing to Children and per the American Beverage Association's ("ABA") guidance for the industry. Furthermore, energy drink manufacturers will not sponsor or promote Children in their Energy Drink marketing campaigns, nor will they sponsor or promote events and/or activities that are intended for an audience predominantly comprised of Children.

- Energy drink manufacturers will not directly sell or market their Energy Drink/s in K-12 schools, in accordance with the industry's School Beverage Guidelines and the ABA's statement regarding the Sale of Energy Drinks in Schools. In addition, energy drink manufacturers will not market or sell their Energy Drink/s at K-12 school events or activities on K-12 school premises, and will use commercially reasonable efforts to encourage third party distributors that deliver and sell their Energy Drink/s to comply with these practices.

- Energy drink manufacturers will not provide Energy Drink samples or product coupons to Children, nor will they provide Energy Drink samples or product coupons in the immediate vicinity of K-12 schools. In addition, energy drink manufacturers will use commercially reasonable efforts to encourage their third-party distributors that deliver and sell their Energy Drink/s to comply with these practices.

- Energy drink manufacturers will not feature Children consuming or promoting Energy Drinks or images featuring persons where those pictured are predominantly Children, on their respective company-managed Energy Drink websites.

- Energy drink manufacturers will not purchase advertising on television, radio or print media and, when audience data are available, Internet and mobile media, in each case where the target audience is predominantly comprised of Children.
- Energy drink manufacturers will not promote or encourage excessive or unduly rapid consumption of

their Energy Drink/s in any marketing or advertising materials.

Energy Drink Reports

- Although not required by law, in a manner consistent with the serious adverse event reporting requirements applicable to dietary supplements pursuant to the Dietary Supplement and Nonprescription Drug Consumer Protection Act, energy drink manufacturers will voluntarily report to the U.S. Food and Drug Administration any serious adverse events reported to them by consumers that are alleged to be associated with consumption of their Energy Drink/s.

Compliance

Energy drink manufacturers will modify their Energy Drink labels and practices as set forth above, as soon as commercially practicable.

* These Proposed Model Guidelines apply to energy drink manufacturers' activities in the United States. Energy drink manufacturers reserve the right to revisit any portion of the Proposed Model Guidelines to the extent required by applicable law or changes in economic and/or competitive conditions affecting the energy drink segment, including non-compliance with the Proposed Model Guidelines by major energy drink manufacturers.