HANDOUT 1.4-B
10/11/16

3 min talk to SCVWB October 11 2016 334 wds

Arlene Goetze, No Toxins for Children photowrite67@yahoo.com

How 'racist' is fluoridation?

Your expert Howard Pollick recently said fluoride should **NOT** go in baby formula -- his former study proved 'poor children never have fewer cavities ."

Black children have the most fluorosis --up to 90% . In '62 the government knew that 'Negros in Grand Rapids had twice as much fluorosis as whites." (1) Ambass. Andrew Young and black ministers are working to bann fluoride in Georgia.

LULAC, (the national group) for Hispanics, wrote 5 years ago **No Hispanic should get fluoride in water.... These kids get 60-70%.**

But these are the 'poverty' kids who can't read or do math. No one seems to care.

When you get a drug , you get the risks.

So when you play doctor, you need to tell parents the risk. The (Amer. Academy) of Pediatric Dentists writes babies should get NONE til 6 months and no more than .25 ppm by age 3. Aren't they one of your experts?

SJ Water Co doesn't not plan to send a second letter .....my daughter doesn't yet have the first. **Public Health started fluoride in 1950 --doesn't tell risks to any other city so why will it do that for you? They won't admit their mistake.**

You are the ones exempt from fluoridating and now that you are forcing it on **'neutral' water companies, you don't accept the need to tell anyone.**

How ethical is that?

The FDA recently told Kirkman Labs to stop selling fluoride tablets -- it's an **'unapproved drug' 'not recognized as safe and effective under the conditions prescribed ...."** Four drugstores have been warned to stop selling them.

So why are you puttng an 'unapproved drug' in tap water without telling consumers its risks? No one will do it for you. It is indeed a RACIST thing that damages children of color. Your actions show us how much you care.

Handout: FDA Letter to Kirkman Labs, 2016
LULAC : Civil Rights Violation Regarding Forced Medication, 2011

Reference: (1) Do you want them drinking a neurotoxic chemical? ***fluoridealert.org***

Department of Health and Human Services logoDepartment of Health and Human Services
Public Health Service
Food and Drug Administration Seattle District Pacific Region
22215 26th Avenue SE, Suite 210
Bothell, WA 98021 Telephone: 425-302-0340 FAX: 425-302-0402

January 13, 2016
In reply refer to Warning Letter SEA 16-07

David K. Humphrey
Chief Executive Officer and President
Kirkman Laboratories, Inc.
10639 Professional Circle
Reno, Nevada 89521

WARNING LETTER

Dear Mr. Humphrey:

The United States Food and Drug Administration (FDA) conducted an inspection of your drug manufacturing facility, Kirkman Laboratories, Inc., located at 6400 Rosewood St., Lake Oswego, Oregon on June 3, 2015, through June 24, 2015. **This inspection revealed that your firm is marketing the following unapproved new drugs:** Kirkman Laboratories, Inc. Flura-Drops ® Sodium Fluoride drops, 2.21 mg; Perry Medical Fluorabon Drops USP; Kirkman Laboratories, Inc. 1.1 mg Cherry Dye-Free Sodium Fluoride Tablets; and Kirkman Laboratories, Inc. 2.21 mg Cherry Dye-Free Sodium Fluoride Tablets, in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 355(a)]. **Additionally, FDA has determined that these products are misbranded drugs in violation of section 502 and 503 of the Act [21 U.S.C. §§ 352 and 353], as detailed below.**

A. Unapproved New Drug Violations

Based on the information collected during the recent inspection, you manufacture and/or **distribute unapproved new drugs** in violation of sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)].

The unapproved new drugs include, but are not limited to:

Kirkman Laboratories, Inc. Flura-Drops® Sodium Fluoride Drops, 2.21 mg (NDC 58223-517), which is labeled "for once daily, self-administered, systemic use as a dental caries preventive in pediatric patients";

Perry Medical Fluorabon Drops USP, 0.25mg (NDC 11763-524), which is labeled "as an aid in the prevention of dental caries";

Kirkman Laboratories, Inc. 1.1 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-678), which is labeled "as an aid in the prevention of dental caries"; and

Kirkman Laboratories, Inc. 2.21 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-679), which is labeled "as an aid in the prevention of dental caries."

The above products are drugs within the meaning of section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)], because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans. Further, as labeled, these drugs are "new drugs" within the meaning of section 201(p) of the Act [21 U.S.C. § 321(p)] **because they are not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in their labeling.** Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. § 355(b) or (j)] is in effect for the drug. **There are no FDA-approved applications on file for the drugs listed above. The marketing of these drugs, or other new drugs, without an approved application constitutes a violation of the Act.[1]**

B. Misbranding Violations

The above products also are **"prescription drugs"** as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], because, in light of their toxicity or potential for harmful effects, or the method of their use, or the collateral measures necessary for their use, **they are not safe for use except under the supervision of a practitioner licensed by law to administer them.1**

Because these prescription drug products are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written for them so that a layman can use them safely for their intended uses. Consequently, the labeling of your firm's unapproved prescription drug products fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(l) of the Act [21 U.S.C. § 352(f)(1)]. Because your drugs lack required approved applications, they are not exempt under 21 CFR 201.115 from the requirements of section 502(f)(1) of the Act. The above products also are misbranded under section 503(b)(4)(A) of the Act [21 U.S.C. § 353(b)(4)(A)], because the labels fail to bear the symbol "Rx Only." The introduction or delivery for introduction into interstate commerce of these drugs therefore violates sections 301(a) of the Act [21 U.S.C. § 331(a)].

C. Conclusions

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence and the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal actions without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts. **You should discontinue marketing all of the unapproved prescription drugs manufactured at your facility immediately**. Additionally, FDA may withhold approval of requests for export certificates or approval of pending new drug applications listing your facility as a manufacturer until the above violations are corrected. A re-inspection may be necessary to verify corrective actions have been completed.

FDA requests that you contact CDER's Drug Shortages Staff immediately at drugshortages@fda.hhs.gov so that we can work with you to meet any obligations **you may have to report discontinuances or interruptions in your drug manufacture,** as required under 21 U.S.C. § 356c(a), and to allow FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Please notify this office in writing within fifteen (15) working days of receiving this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If the corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the timeframe within which the corrections will be completed. Please include copies of any documentation demonstrating that corrections have been made. If you no longer manufacture or market your fluoride products, your response should indicate, including the reasons that, and the date on which, you ceased production.

Your reply should be sent to the following address: U.S. Food and Drug Administration, 22215 26th Avenue SE, Suite 210, Bothell, Washington 98021 to the attention of Maria P. Kelly-Doggett, Compliance Officer. If you have any questions regarding any issues in this letter, please contact Compliance Officer Maria Kelly-Doggett by telephone at 425-302-0427.

Sincerely, /S/

Miriam R. Burbach, District Director

cc: Lawrence A. Newman
Chief Operating Officer Technical & Regulatory Affairs
Kirkman Laboratories, Inc., 6400 Rosewood St., Lake Oswego, Oregon 97035

Fda.gov/aCEel/Enforcement Actions/WarningLetters/2016/ucm 483224.htm

Civil Rights Violation Regarding Forced Medication, 2011 [Abridged]

LEAGUE of UNITED LATIN AMERICAN CITIZENS (LULAC)

WHEREAS, the League of United Latin American Citizens is this nation's oldest and largest Latino organization, founded in Corpus Christi, Texas on February 17, 1929; and
WHEREAS, LULAC throughout its history has committed itself to the principles that Latinos have equal access to opportunities in employment, education, housing and healthcare; and
WHEREAS, LULAC advocates for the well-being of, but not exclusively of, Hispanics throughout our country; and
WHEREAS, safe drinking water is a necessity for life; and
WHEREAS, the purpose of a public water supply is to supply water to the entire community which is composed of people with varying health conditions, in varying stages of life, and of varying economic status; not to forcibly mass medicate the population which is a civil rights violation; and
WHEREAS, fluoridation is mass medication of the public through the public water supply; and
WHEREAS, current science shows that fluoridation chemicals pose increased risk to sensitive subpopulations, including infants, the elderly, diabetics, kidney patients, and people with poor nutritional status; and
WHEREAS, minority communities are more highly impacted by fluorides as they historically experience more diabetes and kidney disease; and
WHEREAS, minorities are disproportionately harmed by fluorides as documented by increased rates of dental fluorosis (disfiguration and discoloration of the teeth); and
WHEREAS, the National Research Council in 2006 established that there are large gaps in the research on fluoride's effects on the whole body; a fact that contradicts previous assurances made by public health officials and by elected officials, that fluorides and fluoridation have been exhaustively researched; and
WHEREAS, the CDC now recommends that non-fluoridated water be used for infant formula (if parents want to avoid dental fluorosis – a permanent mottling and staining of teeth), which creates an economic hardship for large numbers of families, minority and otherwise; and
WHEREAS, the League of United Latin American Citizens (LULAC), founded in 1929, has historically been a champion of the disenfranchised and a leader in the fight for social and environmental justice; and...
WHEREAS, the U.S. Health and Human Services and the EPA (January 2011) have recently affirmed the NRC Study results that citizens may be ingesting too much fluoride and that the exposure is primarily from drinking water...

THEREFORE, BE IT RESOLVED, that LULAC commends efforts by organizations that oppose forced mass medication of the public drinking supplies using fluorides that are industrial grade, toxic waste by-products which contain contaminants (arsenic, lead, mercury) which further endanger life; and
BE IT FURTHER RESOLVED, that LULAC supports efforts by all citizens working to stop forced medication through the public water system because it violates civil rights; and
BE IT FURTHER RESOLVED, that LULAC opposes the public policy of fluoridation because it fails to meet legislative intent; and
BE IT FURTHER RESOLVED, that LULAC demands to know why government agencies entrusted with protecting the public health are more protective of the policy of fluoridation than they are of public health.

Approved this 1st day of July 2011.
Margaret Moran
LULAC National President

Source: Civil Rights Violation REgarding Force Medication, 2011 (Abridgement, 2013)
League of United Latin American Citizens (LULAC)
http://lulac.org/advocacy/resolutions/2011/resolution_Civil_Rights_Violation_Regarding_Forced_Medication/

LEAGUE *of* UNITED LATIN AMERICAN CITIZENS

LIGA de Ciudadanos Latinos Americanos Unidos (LULAC)

Derechos Civiles Violación relacionada con medicamentos forzoso, 2011

Compendio (2013) aprobado por Henry Rodriguez LULAC Concilio Zapatista 4383

POR CUANTO, la Liga de Ciudadanos Latinoamericanos Unidos es la organización latina más antigua y más grande de lanación, fundada en Corpus Christi, Texas el 17 de febrero 1929 y
CONSIDERANDO que, LULAC en toda su historia se ha comprometido a los principios que los latinos tienen igualdad de acceso a oportunidades en el empleo, la educación, la vivienda y la asistencia sanitaria, y
CONSIDERANDO que, LULAC aboga por el bienestar de, pero no exclusivamente, de los hispanos en todo el país, y
CONSIDERANDO, que el agua potable es una necesidad para la vida, y
CONSIDERANDO, que la finalidad de un servicio público es para abastecer de agua a toda la comunidad que se compone de personas con diferentes problemas de salud, en diferentes etapas de la vida, y de diferente nivel económico, no a la masa por la fuerza medicar a la población, que es una violación de derechos civiles, y
CONSIDERANDO, que la fluoración es la medicación masiva de la población a través del servicio público, y
CONSIDERANDO, que la ciencia actual demuestra que los productos químicos fluoración suponen un mayor riesgo para las subpoblaciones sensibles, incluyendo a los bebés, los ancianos, los diabéticos, los pacientes renales y personas con mal estado nutricional, y
CONSIDERANDO, que las minorías están más afectados por fluoruros, ya que históricamente sufren más la diabetes y la enfermedad renal, y
CONSIDERANDO, que las minorías son desproporcionadamente perjudicados por fluoruros como está documentado por el aumento de las tasas de dental fluorosis (desfiguración y la decoloración de los dientes); y
CONSIDERANDO que el Consejo Nacional de Investigación en 2006 estableció que hay grandes lagunas en la nvestigación sobre efectos del fluoruro en todo el cuerpo, hecho que contradice las garantías anteriores realizados por funcionarios de salud pública por los funcionarios electos, que los fluoruros y la fluoración se han investigado exhaustivamente, y
CONSIDERANDO, que el CDC ahora recomienda utilizar el agua no fluorada para la fórmula infantil (si los padres quieren evitar la fluorosis dental - un moteado permanente y la tinción de los dientes), que crea una carga económica para las grandes número de familias, las minorías y de otra manera, y
POR CUANTO, la Liga de Ciudadanos Latinoamericanos Unidos (LULAC), fundada en 1929, ha sido históricamente un campeón de los desposeídos y un líder en la lucha por la justicia social y ambiental, y ...
CONSIDERANDO, que la Salud y Servicios Humanos de EE.UU. y de la EPA (enero de 2011) han afirmado recientemente el NRC Los resultados del estudio que los ciudadanos pueden estar ingiriendo demasiado fluoruro y que la exposición es principalmente por beber agua ...

POR LO TANTO, SE RESUELVE, que LULAC alaba los esfuerzos de las organizaciones que se oponen a la masa forzado medicamentos de las fuentes de agua potable públicos usando fluoruros que se encuentran, los desechos tóxicos de grado industrial de los subproductos que contener contaminantes (arsénico, plomo, mercurio), que ponen en peligro aún más la vida, y
SE RESUELVE ADEMÁS, que LULAC apoya los esfuerzos de todos los ciudadanos que trabajan para poner fin a la medicación forzada a través del sistema público de agua debido a que viola los derechos civiles y
SE RESUELVE ADEMÁS, que LULAC se opone a la política pública de la fluoración, ya que no cumple intención del legislador, y
SE RESUELVE ADEMÁS, que las demandas de LULAC para saber por qué los organismos gubernamentales encargados de la protección de la salud pública son más estrictas para proteger la política de fluoración de lo que son la salud pública.

Aprobado este primero día de julio de 2011.

Margaret Moran
Presidente Nacional de LULAC

Fuente:: Violación de Derechos Civiles relacionada con medicamentos forzoso, 2011 [Compendio, 2013]
Liga de Ciudadanos Latinoamericanos Unidos (LULAC)
<http://lulac.org/advocacy/resolutions/2011/resolution_Civil_Rights_Violation_Regarding_Forced_Medication/>