

Complaint

IN THE MATTER OF

**KRIS A. PLETSCHKE, INDIVIDUALLY AND
DOING BUSINESS AS RAW HEALTH**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4040; File No. 0223070**Complaint, February 22, 2002--Decision, February 22, 2002*

This consent order addresses practices used by Respondent Kris A. Pletschke, individually and doing business as Raw Health, in marketing Colloidal Silver" – a dietary supplement allegedly containing submicroscopic particles of silver – intended to be taken for the cure and treatment of more than 650 diseases. The order, among other things, prohibits the respondent from misrepresenting any claims that Colloidal Silver – or any food, dietary supplement, drug, device, or health-related service or program – has been medically proven to kill disease-causing organisms or any number of infections in the body. The order also requires the respondent to possess and rely upon competent and reliable scientific evidence to substantiate representations that Colloidal Silver or any covered product (1) is effective in treating 650 diseases and health-related conditions; (2) kills the HIV virus and can be used as an antibiotic for all acquired diseases of active AIDS; (3) is superior to antibiotics in killing disease-causing organisms and the treatment of burns; (4) protects and strengthens the immune system; (5) can safely be used on open wounds, sprayed into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes; (6) has no side effects, even at double or triple the normal dose of 260 parts per million, and is safe for children and pregnant and nursing women; or (7) has any health, performance, safety, or efficacy benefits. In addition, the order prohibits the respondent from misrepresenting, including by means of metatags, the existence, contents or interpretation of any test, study, or research. The order also requires the respondent to offer refunds to all of his past consumers and wholesale purchasers of Colloidal Silver, and to file a sworn affidavit with the Commission concerning his compliance with the refund provisions.

Participants

For the Commission: *James T. Rohrer, Cindy A. Liebes, and
Andrea L. Foster.*

For the Respondent: *Kris A. Pletschke, pro se.*

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The Federal Trade Commission, having reason to believe that Kris A. Pletschke ("respondent"), individually, and doing business as Raw Health, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Kris A. Pletschke is a resident of Oregon. His principal office or place of business is 11355 SW 14th St., Beaverton, OR 97005. Individually, or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the business operating under the trade name "Raw Health," including the acts and practices alleged in this complaint.
- 2.a. Respondent has promoted, advertised, labeled, offered for sale, sold and distributed directly to the public a colloidal silver liquid product called *Colloidal Silver*, various vitamin, mineral, and herbal products, and other health products, including by means of an Internet Web site, www.rawhealth.net, that provides product and purchase information and advertising and promotional claims.
- 2.b. Respondent's *Colloidal Silver* is purportedly a liquid containing 260 ppm silver, enhanced with gold, quartz, and emerald essence in a water solution, that can be used for various therapeutic purposes through oral ingestion, intravenous administration, nasal spray, anal and vaginal administration, or topical application. *Colloidal Silver* is either a "food" or "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.
4. Respondent has disseminated or has caused to be disseminated advertisements or promotional materials for *Colloidal Silver*,

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through, among other media, websites on the Internet, including but not necessarily limited to the attached Exhibits A and B. These advertisements contain the following statements, among others:

A.

Add item: Colloidal Silver 1-(8oz 260ppm)
.\$18.00 ea.

Add item: Colloidal Silver 4-(8oz 260ppm)
.\$17.50 ea.

Add item: Colloidal Silver 8-(8oz 260ppm)
.\$17.00 ea.

Enhanced with gold, quartz, and emerald essences. Clear and odorless. You won't find your local natural foods store carrying this enhanced combination or nearly this concentration (ppm). Colloidal Silver Water is the only naturally occurring and most effective anti-viral and anti-bacterial substance known; it is beyond pharmaceutical antibiotics. Great for traveling to purify the drinking water. Helps to accelerate wound healing, eye infections, cold-flu, douching, candida, & more.

www.rawhealth.net/cleanse.htm

Exhibit A

B.

COLLOIDAL SILVER FABULOUS FACTS -
& Frequently Asked Questions

* * *

Colloidal Silver is a pure all-natural substance consisting of sub-microscopic clusters of silver held in a suspension of pure

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ionized water by a tiny electric charge placed on each particle. Colloidal Silver is a tasteless, odorless, nontoxic, pure, natural substance consisting of submicroscopic clusters of silver particles, suspended by a tiny electric charge placed on each particle within a suitable liquid. The molecules size is .00001 microns or 1.26 angstroms in diameter which is very small. The particles do not settle but remain suspended since the electric charge exerts more force than gravity on each particle. Colloidal is the form of choice for silver delivery since the body must convert a crystalline solution to a colloid before it can be assimilated. Taken daily, it is a powerful adjunct to our immune system. It kills harmful disease causing organisms and aids healing.

* **

WHAT ARE THE KEY CHARACTERISTICS?

Colloidal Silver is non-toxic, non-addictive and has no side-effects. The body develops no tolerance and one cannot overdose. Colloidal Silver cannot cause harm to the liver, kidneys or any other organ in the body. It is safe for pregnant and nursing women and even aids the developing fetus in growth and health as well as easing the mother's delivery and recovery. Colloidal Silver is odorless, tasteless, non-stinging, harmless to eyes, contains no free radicals, is harmless to human enzymes and has no reaction with other medications. It improves digestion, aids in the regeneration of damaged cells and tissues, helps prevent colds, flu and organism caused diseases [*sic*]. It has been reported to rapidly subdue inflammation and promote faster healing. The body needs Colloidal Silver to fight disease causing organisms and to aid healing. Taken daily, Colloidal Silver provides a second immune system resulting in more energy, vitality, vigor, relaxation, faster healing and reduced bodily toxins.

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HOW DOES COLLOIDAL silver WORK?

According to medical journals from around the world, it disables the particular enzyme that all one celled bacteria, fungi and viruses use for their oxygen metabolism. The presence of Colloidal Silver near a virus, fungus, bacterium or any other single celled pathogen disables its oxygen metabolism enzyme, its chemical lung, so to say. It suffocates them in six minutes or less after initial contact; the pathogen suffocates and dies and is cleared out of the body by the immune, lymphatic and elimination systems. Colloidal Silver co-mingles with the blood and enters the cells to seek out and destroy harmful organisms. This phenomenon was recently demonstrated in tests at UCLA Medical Lab. Trace amounts protect and strengthen the immune system. . . .

Thus **Colloidal Silver is absolutely safe** for humans, reptiles, plants and all multi-celled living matter. Unlike with antibiotics, resistant strains have never been known to develop. In fact, antibiotics are only effective against perhaps a dozen forms of bacteria and fungi, but never viruses. Because no known disease causing organism can live in the presence of even minute traces of the chemical element of metallic silver, colloidal silver is effective against more than 650 different disease causing pathogens. . . .

Medical journal reports and documented studies spanning the past 100 years indicate no known side-effects from oral or IV administration of colloidal silver in animal or human testing. Colloidal silver has been used with good results under the most demanding health care circumstances. Without overstating the case, it may be time to recognize colloidal silver as not only the safest medicine on Earth but also the most powerful. . . .

Colloidal Silver is truly a safe, natural remedy for many of mankind's ills. Since viruses like Ebola and Hunta, or even the

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dreaded "flesh-eating bacteria" are in the end merely hapless viruses and bacteria. . . .

USES OF COLLOIDAL SILVER

For several decades the clinical use of Silver have been proven in the treatment of burns as well as eye, ear, nose, throat, vaginal, rectal and urinary tract infections. Silver has been prescribed in medicine as an aid to the brain, reproductive disorders in women and the circulatory system. It has been used as a remedy for mental imbalances, sleepwalking and anorexia nervosa. Additional uses include the treatment of AIDS, allergies, anthrax, arthritis, blood poisoning, boils, wounds of the cornea, chronic fatigue, cerebral spinal meningitis, candida, cholera, colitis, cystitis, diabetes, diphtheria, dysentery, enlarged prostate, gonorrhea, herpes, hepatitis, infantile diseases, lesions, leukemia, lupus, Lyme disease, parasites, dental plaque remover, rheumatism, ringworm shingles, skin cancer, staph and strep infections, stomach flu, thyroid conditions, tonsillitis, toxemia, stomach ulcers and whooping cough to name a few. It is even used as a natural under arm deodorant and handy for virtually every medical circumstance for humans, plants and animals around the home and farm.

INGESTING COLLOIDAL SILVER

Taken orally, the silver solution is absorbed from the mouth into the bloodstream then transported quickly to the body cells. Swishing the solution under the tongue briefly before swallowing ensures fast absorption[.] In three to four days the silver will have accumulated in the tissues sufficiently for benefits to begin. Since Colloidal Silver is eliminated by the kidneys, lymph system and bowel after three weeks, a regular daily intake is recommended as a protection against dangerous pathogens. In cases of minor burns, an accumulation of Colloidal Silver can hasten healing, reducing scar tissue and

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infection. The lives of millions of people susceptible to chronic low-grade infections can be enhanced by this powerful preventative health measure[.]

TOPICAL APPLICATION OF COLLOIDAL SILVER

(concentration/ parts-per-million determines your actual dosage. consult your bottle.)

Colloidal Silver is painless on burns, cuts, abrasions, in open wounds, in the nostrils for a stuffy nose, arid [*sic*] even in a persons eyes because unlike antiseptics, it does not destroy tissue cells. It is perfect with cosmetics, creams and lotions. Spray on then add your favorite beauty product. A few drops on a Q-tip or band-aid may be used to disinfect any wound or sore. Liquid silver is administered orally and can also be injected. It can be used vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes. To start, take one teaspoon per day, for seven days, then reduce to half a teaspoon per day. Children should use proportionally smaller doses. For cold and flu symptoms up to a tablespoon three times daily is recommended. Overdosing should not be of concern even if more than the recommended dose is administered. After a few days of use, one might experience a detoxification effect in the form of feeling sluggish or mild aches. Consumption of water will cause these symptoms to disappear.

It is safe for pregnant and nursing women and is known to aid the developing fetus in growth. It will not generate free radicals or interfere with enzyme activity. . . .

A 65-year-old diabetic cut himself on the leg. He washed and bandaged it but, as often happens with diabetes, the pain persisted. The cut grew into a sore. Soon it became bigger than the bandage and he had to apply a dressing. Still, it

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grew bigger and ugly. In desperation he went to a clinic. His sore was diagnosed as a stasis ulcer. For a year, one treatment after another was tried. Nothing including penicillin and sulfonamide, could heal the ulcer. If his condition had continued unchecked [his] leg probably would have been amputated. But finally he was referred to a burn clinic that treated skin ulcers with a silver compound. This promptly stopped the growth of all bacteria. In less than two months, the ulcer was completely healed. Science Digest-March 1978.

FOR CHRONIC OR SERIOUS CONDITIONS

Take double or triple the recommended amount for 10 to 45 days, then drop to the maintenance dose. If your body is extremely ill or toxic do not be in a hurry to clear up everything at once. If pathogens are killed off too quickly, the body's five eliminatory channels, i.e., the liver, kidneys, skin, lungs and bowel, may be temporarily overloaded, causing flu-like conditions, headache, extreme fatigue, dizziness, nausea or aching muscles. Ease off on the Colloidal Silver to the maintenance amount and increase your distilled water intake. Regular bowel movements are a must in order to relieve the discomforts of detoxification. Resolve to reduce sugar and saturated fats from the diet, and exercise more. Given the opportunity, the body's natural ability to heal will amaze you.

WHAT ABOUT COLLOIDAL SILVER FOR AIDS?

Since in active AIDS, the suppressed immune system of the body is open to all kinds of disease. Colloidal Silver is the perfect nontoxic substance used for its wide spectrum antibiotic effect. A researcher at Brigham Young University sent Colloidal Silver to two different labs including UCLA Medical Center, and reported "It not only killed the HIV virus but every virus that was tested in the labs. According

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to FDA rules, Colloidal Silver cannot be used for treating the HIV virus, but it could be used as an antibiotic for all acquired diseases of active AIDS.

HAS IT BEEN CLINICALLY TESTED?

YES! Colloidal Silver has been successfully tested at the UCLA Medical Labs where it killed every virus on which it was tested.

WHAT DOES THE FDA SAY?

According to the United States Government Food and Drug Administration Colloidal Silver may continue to be marketed and used as it was originally intended. Colloidal Silver exceeds FDA recognized standards for safety. In a September 13, 1991 letter written by Harold Davies, U.S. Food and Drug Administration Consumer Safety Officer stated that FDA has no jurisdiction regarding a pure, mineral element. No one should worry about the FDA (Food and Drug Administration) being put in charge of this home remedy. Colloidal Silver is grand fathered as a pre 1938 healing modality. This makes it exempt from FDA jurisdiction.

COLLOIDAL SILVER VERSUS PHARMACEUTICAL ANTIBIOTICS

Interest in Colloidal Silver has increased recently because illness causing organisms do not build up a resistance to Colloidal Silver the way they do to pharmaceutical antibiotics. Antibiotics are becoming less effective as resistance to them grows. Artificial antibiotics kill, on average 6 different disease organisms but Colloidal Silver is known to kill over 650 diseases without any harmful side effects or toxicity. The Los Angeles Times states "In the last decade, a broad resistance to antibiotics has begun to emerge. Because bacteria can transfer genes among themselves, experts only expect the resistance to

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grow, The potential nightmare is an Andromeda strain, which is immune to all antibiotics and could wreak havoc *Arsenal of Antibiotics Failing as Resistant Bacteria Develop* October 23, 1994.

* * *

Jim Powell reported in the Science Digest article quoted above, that an antibiotic kills perhaps 7 different disease organisms, but silver kills some 650. Resistant strains fail to develop. Moreover, silver is nontoxic! The comeback of silver in medicine began in the 1970's. The late Dr. Carl Moyer, chairman of Washington University's Department of Surgery received a grant to develop a better treatment for burn victims. Dr. Harry Margraf of St. Louis, as the chief biochemist, worked with Dr. Moyer and other surgeons to find an antiseptic strong enough yet safe enough to use over larger areas of the body. Dr. Margraf reviewed 22 antiseptic compounds and found drawbacks in all of them. He noted that many of these antibiotics were ineffective against a number of harmful bacteria, including the biggest killer in burn cases a greenish blue bacterium called *Pseudomonas aeruginosa*. In extensive trials silver proved to be the most effective treatment and is currently used in all major burn [sic] centers in the United States. The safest proven germ fighter! SILVER IS USED IN ALL MAJOR BURN CENTERS IN THE UNITED STATES. UCLA MEDICAL LABS FOUND IT EFFECTIVE ON EVERY VIRUS THEY TESTED IT ON.

WHAT DO HEALTH PROFESSIONALS SAY ABOUT COLLOIDAL SILVER?

According to Dr. Evan of Illinois, . . . colloidal silver has provided excellent removal of abnormal intestinal bacteria also it has proved to be a great adjunct to our *Candida albicans*, Epstein Barr Virus and Chronic Fatigue Syndrome protocols.

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* * *

Dr. Henry Crooks in Use of Colloids in Health-Disease found that silver in the colloidal state is highly germicidal, quite harmless to humans and absolutely nontoxic. From his bacteriological experiments with silver he concluded "I know of no microbe that is not killed in laboratory experiments in six minutes."

Dr. Bjorn Nordenstrorn of the Larolinska Institute, Sweden has successfully used silver as a component in his cancer treatments for many years. Dr. Leonard Keene Hirschberg, M. D. at John Hopkins states, "Speaking generally, the colloidal metals are especially remarkable for their beneficial action in infective states."

Dr, Richard L. Davies, executive director of the Silver Institute, which monitors silver technology in 37 countries, reports: "In four years we've described 87 important new medical uses for silver. We're just beginning to see to what extent silver can relieve suffering."

The March 1978 issue of *Science Digest*, in an article, "Our Mightiest Germ Fighter, "reported:" Thanks to eye-opening research, silver is emerging as a wonder of modern medicine. An antibiotic kills perhaps a half-dozen different disease organisms, but silver kills some 650. Resistant strains fail to develop. Moreover, silver is virtually non-toxic. "The article ended with a quote by Dr. Harry Margraf, a biochemist and pioneering silver researcher who worked with the late Carl Moyer, M.D., chairman of Washington University's Department of Surgery in the 1970s: "Silver is the best all-around germ fighter we have."

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Since the body is known to have a vital need for silver to maintain both the immune system and the production of new healthy cells, and due to the harmonious nature of colloids entering the body, it stands within reason that colloidal silver may be harmless. Just to prove the point make a sixteen-ounce solution of well over 250 ppm and drink it. It's plenty safe. This makes sense according to Capitol Drugs pharmacist Ron Barnes, PhD. "Many strains of pathogenic microbes, viruses, fungi, bacteria or any other single celled pathogen resistant to other antibiotics are killed on contact by colloidal silver, and are unable to mutate. However, it does not harm tissue-cell enzymes and friendly bacteria.

www.rawhealth.net/silver.htm

Exhibit B

5. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that:

- A. *Colloidal Silver* is effective in treating or curing 650 diseases.
- B. *Colloidal Silver* eliminates all pathogens in the human body in six minutes or less.
- C. *Colloidal Silver* has been medically proven to kill every destructive bacterial, viral and fungal organism in the body, including anthrax, Ebola, Hunta, and "flesh-eating bacteria."

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6. In truth and in fact, *Colloidal Silver* is not effective in treating or curing 650 diseases; *Colloidal Silver* does not eliminate all pathogens in the human body in six minutes or less; and *Colloidal Silver* has not been medically proven to kill destructive bacterial, viral, or fungal organisms in the body. In addition, the FDA issued a final rule, effective September 16, 1999, finding and establishing that all OTC drug products containing colloidal silver ingredients or silver salts for internal or external use are not generally recognized as safe and effective. Therefore, the representations set forth in Paragraph 5 were, and are, false and misleading.

7. Through the means described in Paragraphs 4, respondent has represented, expressly or by implication, that:

- A. *Colloidal Silver* is effective in treating 650 diseases and health-related conditions, including AIDS, allergies, anthrax, arthritis, blood poisoning, boils, wounds of the cornea, chronic fatigue, cerebral spinal meningitis, candida, cholera, colitis, cystitis, dental plaque, diabetes, diphtheria, dysentery, enlarged prostate, gonorrhea, herpes, hepatitis, infantile diseases, lesions, leukemia, lupus, Lyme disease, parasites, rheumatism, ringworm shingles, skin cancer, staph and strep infections, stomach flu, thyroid conditions, tonsillitis, toxemia, stomach ulcers and whooping cough.
- B. *Colloidal Silver* kills the HIV virus and can be used as an antibiotic for all acquired diseases of active AIDS.
- C. *Colloidal Silver* is superior to antibiotics in killing disease-causing organisms and the treatment of burns.
- D. *Colloidal Silver* protects and strengthens the immune system.

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- E. *Colloidal Silver* can safely be used on open wounds, sprayed into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes.
- F. *Colloidal Silver* has no side effects, even at double or triple the normal dose of 260 ppm, and it is safe for children and pregnant and nursing women.
- G. *Colloidal Silver* aids the growth and health of the developing fetus and eases delivery and recovery.

8. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that he possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 7, at the time the representations were made.

9. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 7 at the time the representations were made. For example, there is no competent and reliable scientific evidence that *Colloidal Silver* is effective in treating or curing any disease, including AIDS, anthrax, or arthritis; that *Colloidal Silver* kills the HIV virus and can be used as an antibiotic for all acquired diseases of active AIDS, or that it is superior to antibiotics in killing disease-causing organisms. In addition, there is no competent and reliable scientific evidence that *Colloidal Silver* is safe for oral ingestion, topical application, and IV administration or that *Colloidal Silver* has no side effects. Therefore, the representation set forth in Paragraph 8 was, and is, false or misleading.

10. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the

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making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twenty-second day of February, 2002, has issued this complaint against respondent.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violations of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, and admission by the respondent of all the jurisdictional facts set forth in the draft complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement, now in further conformity with the procedure prescribed in Section 2.34(c) of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Kris A. Pletschke is an individual doing business and residing at 11355 SW 14th St., Beaverton, OR 97005 under the trade name "Raw Health."
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

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ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. “Competent and reliable scientific evidence” shall mean tests, analyses, research, studies, or other evidence based on 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.
2. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
3. A requirement that respondent “notify the Commission,” “file with the Commission,” or “deliver to the Commission” shall mean that the respondent shall send the necessary information via first-class mail, costs prepaid, to the Associate Director for Division of Enforcement, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Attention: In the Matter Kris A. Pletschke.
4. “Person” shall mean a natural person, organization or other legal entity, including a partnership, corporation, proprietorship, association, cooperative, or any other group acting together as an entity.
5. Unless otherwise specified, “respondent” shall mean Kris A. Pletschke, individually, and d/b/a Raw Health, his agents, representatives, and employees.
6. “Colloidal Silver product” shall mean any product containing or purporting to contain colloidal silver or silver salts, including but not limited to Raw Health’s *Colloidal Silver*.

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7. "Distributor" shall mean any purchaser or other transferee of any product, service, or program covered by this order who acquires product or service from respondent, with or without valuable consideration, and who sells, or who has sold, such product or service to other sellers or to consumers, including but not limited to individuals, retail stores, or catalogs.
8. "Food," "drug," and "device" shall mean as "food," "drug," and "device" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
9. "Covered product or service" shall mean any food, dietary supplement, drug, device, or health-related service or program.
10. "Endorsement" shall mean as "endorsement" is defined in 16 C.F.R. § 255.0(b).

I.

IT IS HEREBY ORDERED that respondent, directly or through any partnership, corporation, subsidiary, division, trade name, or other device, including franchisees, licensees, or distributors, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any *Colloidal Silver* product or any covered product or service in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, that such product or service is effective in treating or curing 650 diseases; eliminates all pathogens in the human body in six minutes or less; or has been medically proven to kill any destructive bacterial, viral and fungal organism in the body, including anthrax, Ebola and Hunta, or "flesh-eating bacteria."

II.

IT IS HEREBY FURTHER ORDERED that respondent, directly or through any partnership, corporation, subsidiary, division, trade name, or other device, including franchisees, licensees, or distributors, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of

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any *Colloidal Silver* product, or any covered product or service in or affecting commerce, shall not make any representation, in any manner, including by means of endorsements, expressly or by implication:

- A. That any such product or service is effective in treating any disease or health-related condition, including, but not limited to, AIDS, allergies, anthrax, arthritis, blood poisoning, boils, wounds of the cornea, chronic fatigue, cerebral spinal meningitis, candida, cholera, colitis, cystitis, dental plaque, diabetes, diphtheria, dysentery, enlarged prostate, gonorrhea, herpes, hepatitis, infantile diseases, lesions, leukemia, lupus, Lyme disease, parasites, rheumatism, ringworm shingles, skin cancer, staph and strep infections, stomach flu, thyroid conditions, tonsillitis, toxemia, stomach ulcers and whooping cough;
- B. That any such product or service kills the HIV virus or can be used as an antibiotic for any acquired diseases of active AIDS;
- C. That any such product or service is superior to antibiotics in killing disease-causing organisms or the treatment of burns;
- D. That any such product or service protects or strengthens the immune system;
- E. That any such product or service can be used safely on open wounds, sprayed into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs, or dropped into the eyes;
- F. That any such product or service has no side effects or that it is safe for children, or pregnant or nursing women;
- G. That any such product or service aids the growth or health of the developing fetus or eases delivery or recovery;

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- H. That any such product or service is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or
- I. About the health benefits, performance, safety, or efficacy of any such product or service;

unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondent, directly or through any partnership, corporation, subsidiary, division, trade name, or other device, including franchisees, licensees or distributors, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not misrepresent, in any manner, including by means of metatags, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such product under any tentative final or final standard promulgated by the Food and Drug Administration. Nor shall it prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

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V.

IT IS FURTHER ORDERED that respondent shall:

- A. Within seven (7) days after service of this order upon respondent, deliver to the Commission a list, in the form of a sworn affidavit, of all distributors who purchased *Colloidal Silver* on or after January 1, 1999, directly from respondent or indirectly through one of respondent's other distributors. Such list shall include each distributor's name and address, and, if available, the telephone number and email address of each distributor.
- B. Within seven (7) days after service of this order upon respondent, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased *Colloidal Silver* on or after January 1, 1999, directly from respondent or indirectly through one of respondent's distributors. Such list shall include each consumer's name and address, and, if available, the telephone number and email address of each consumer and the full purchase price paid, including shipping, handling, and taxes, for *Colloidal Silver* purchased from respondent.
- C. Within thirty (30) days after service of this order upon respondent, send by first class mail, with postage prepaid, an exact copy of the notice attached hereto as Attachment A, showing the date of mailing, to each distributor who purchased *Colloidal Silver* from respondent between January 1, 1999 and the date of service of this order. This mailing shall not include any other document.
- D. Within thirty (30) days after service of this order upon respondent, send by first class mail, with postage prepaid, an exact copy of the notice attached hereto as Attachment B, showing the date of mailing, to each consumer who purchased *Colloidal Silver* between January 1, 1999 and the date of service of this order. This mailing shall not include any other document.

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VI.

IT IS FURTHER ORDERED that respondent shall refund the full purchase price paid of the *Colloidal Silver*, including shipping and handling and applicable taxes, to each consumer whose initial request for a refund is received by respondent within ninety (90) days after the date of mailing as indicated on Attachment B pursuant to subpart V.D. of this order. Respondent shall refund the full purchase price under the following terms and conditions:

- A. If respondent's diligent inquiry and examination of respondent's books and records reasonably substantiates the consumer's claim of purchase or the consumer provides proof of purchase, including but not limited to any of the following: return of goods or packaging, canceled check[s], credit card invoice[s], or receipt[s], the refund shall be paid within fifteen (15) business days of respondent's receipt of the refund request.
- B. If the consumer makes a timely request for a refund but neither of the conditions of subpart A is satisfied, respondent shall provide the consumer within fifteen(15) days of receipt of the request for refund, a declaration of purchase together with a stamped and addressed return envelope, and advise the consumer that respondent will provide a prompt refund if the consumer completes and return the signed declaration to the respondent within fifteen (15) days of consumer's receipt of the notice. The declaration shall be substantially in the form of the declaration attached hereto as Attachment C. The refund shall be paid within fifteen (15) business days of respondent's receipt of the consumer's completed declaration.

Refund requests shall be sent to Kris A Pletschke at 11355 SW 14th Street, Beaverton, OR 97005.

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VII.

IT IS FURTHER ORDERED that respondent shall, no later than one hundred and eighty (180) days after the date of service of this order, deliver to the Commission a monitoring report, in the form of a sworn affidavit executed on behalf of respondent. This report shall specify the steps respondent has taken to comply with the terms of Parts V. and VI. of this order and shall state, without limitation:

- A. The name and address of each consumer to whom respondent sent the notice attached hereto as Attachment B as required under subpart V.D;
- B. The name and address of each consumer from whom respondent received a refund request;
- C. The date on which each request was received and the amount of the refund requested;
- D. The amount of the refund provided by respondent to each such consumer;
- E. The status of any disputed refund request and the identification of each consumer whose refund request is disputed, by name, address, and amount of the claim; and
- F. The total amount of refunds paid by respondent.

VIII.

IT IS FURTHER ORDERED that respondent, for ten (10) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;

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- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

IX.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities as stated above. Respondents shall maintain and upon request make available to the Commission for inspection and copying each such signed and dated statement.

X.

IT IS FURTHER ORDERED that respondent, directly or through any partnership, corporation, subsidiary, division, trade name, or other device, including franchisees, licensees, or distributors shall:

- A. For a period of five (5) years following the entry of this order, send a copy of the notice attached hereto (Attachment A) by first class certified mail, return receipt requested, to any distributor of *Colloidal Silver* or any other covered product or service, ***provided, however,*** that the requirement

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of this subpart shall not apply to any distributor who received a copy of the notice attached hereto (Attachment A) pursuant to the requirements of subpart V.C of this order.

- B. Institute a reasonable program of surveillance adequate to reveal whether any of respondent's distributors are disseminating advertisements or promotional materials that contain any representation about *Colloidal Silver* or any other covered product or service manufactured by or purchased from respondent, that is prohibited by Parts I through III of this order.
- C. Terminate all sales of *Colloidal Silver* or any other covered product or service to any distributor who is engaged in disseminating advertisements or promotional materials that contain any representation about *Colloidal Silver* or any other covered product or service manufactured by or purchased from respondent, that is prohibited by Parts I through III of this order, once respondent knows or should know that the distributor is or has been engaged in such conduct.

XI.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any change with regard to Raw Health that may affect compliance obligations arising under this order, including but not limited to its incorporation; and if incorporated, its creation, dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. ***Provided, however,*** that, with respect to any proposed change about which respondent learns less than thirty (30) days prior to

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the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge.

XII.

IT IS FURTHER ORDERED that respondent, within five (5) days of entry of this order, shall notify the Commission of (1) his residence address and mailing address; (2) his telephone number(s); (3) if applicable, the names of his employer and supervisor(s); and (4) his duties and responsibilities.

XIII.

IT IS FURTHER ORDERED that respondent, for a period of ten (10) years after the date of entry of this order, shall notify the Commission of (1) any changes in his residence address, mailing address, or business address; (2) the discontinuance of his current business or employment; and (3) his affiliation with any new business or employment. Notice of changes in employment status shall include: (1) the new employer's name, address and telephone number; (2) the full names of the employer's principals; (3) if applicable, the names of respondent's supervisors; and (4) a description of the employer's activities, and respondent's duties and responsibilities.

XIV.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which respondent has complied and is complying with this order.

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XV.

This order will terminate on February 22, 2022, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; ***provided, however***, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission

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ATTACHMENT A

LETTER SENT TO DISTRIBUTORS WITH WHOM
RESPONDENT HAS DONE BUSINESS BETWEEN
JANUARY 1, 1999
AND THE DATE OF SERVICE OF THIS ORDER

[To Be Printed on Kris Pletschke's or Raw Health's letterhead]

[NAME AND ADDRESS OF RECIPIENT]

[DATE]

Dear [DISTRIBUTOR'S NAME]:

This letter is to inform you that Raw Health recently settled a civil dispute with the Federal Trade Commission regarding its advertising for *Colloidal Silver*. Among other things, the settlement requires us to notify distributors of the settlement.

Importantly, the settlement requires us to monitor our distributors and terminate all distributors making prohibited claims for *Colloidal Silver* or any other dietary supplement, food or drug purchased from us for resale.

According to the FTC complaint, our advertising materials falsely claimed that *Colloidal silver* (1) is effective in treating or curing 650 diseases; (2) eliminates all pathogens in the human body in six minutes or less; (3) has been medically proven to kill every destructive bacterial, viral and fungal organism in the body, including anthrax, Ebola, Hunta, and "flesh-eating bacteria." In addition, the FTC complaint alleged that we did not have a reasonable basis to claim that *Colloidal Silver* (1) is effective in treating AIDS, allergies, anthrax, arthritis, blood poisoning, boils, wounds of the cornea, chronic fatigue, cerebral spinal meningitis,

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candida, cholera, colitis, cystitis, diabetes, diphtheria, dysentery, enlarged prostate, gonorrhea, herpes, hepatitis, infantile diseases, lesions, leukemia, lupus, Lyme disease, parasites, dental plaque, rheumatism, ringworm shingles, skin cancer, staph and strep infections, stomach flu, thyroid conditions, tonsillitis, toxemia, stomach ulcers and whooping cough; (2) kills the HIV virus and can be used as an antibiotic for all acquired diseases of active AIDS; (3) is superior to antibiotics in killing disease-causing organisms and the treatment of burns; (4) protects and strengthens the immune system; (5) can safely be used on open wounds, sprayed into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes; (6) has no side effects, even at double or triple the normal dose of 250 ppm, and is safe for children and pregnant and nursing women; and (7) aids the growth and health of the developing fetus and eases delivery and recovery.

Please sign, date, and return this letter to Kris Pletschke at 11355 SW 14th Street, Beaverton, OR 97005. A copy of this letter has been provided for your files. If you have any questions or you want a copy of the FTC order, please contact [Insert name and telephone number of respondent's contact]. Thank you for your anticipated cooperation and assistance.

Kris Pletschke

ACKNOWLEDGMENT AND AGREEMENT

The undersigned acknowledges receipt of this letter.

Date:

Print Full Name:

Signature:

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ATTACHMENT B

LETTER SENT TO CONSUMERS WITH WHOM
RESPONDENT HAS DONE BUSINESS BETWEEN
JANUARY 1, 1999 AND THE DATE OF SERVICE OF THIS
ORDER

[To Be Printed on Kris Pletschke's or Raw Health's letterhead]

[NAME AND ADDRESS OF RECIPIENT]

[DATE]

Dear [CUSTOMER'S NAME]:

This letter is to inform you that Raw Health recently settled a civil dispute with the Federal Trade Commission regarding its advertising for *Colloidal Silver*. Among other things, the settlement requires us to notify consumers of the settlement and offer refunds to persons who purchased *Colloidal Silver*.

According to the FTC complaint, our advertising materials falsely claimed that *Colloidal silver* (1) is effective in treating or curing 650 diseases; (2) eliminates all pathogens in the human body in six minutes or less; (3) has been medically proven to kill every destructive bacterial, viral and fungal organism in the body, including anthrax, Ebola, Hunta, and "flesh-eating bacteria." In addition, the FTC complaint alleged that we did not have a reasonable basis to claim that *Colloidal Silver* (1) is effective in treating AIDS, allergies, anthrax, arthritis, blood poisoning, boils, wounds of the cornea, chronic fatigue, cerebral spinal meningitis, candida, cholera, colitis, cystitis, diabetes, diphtheria, dysentery, enlarged prostate, gonorrhea, herpes, hepatitis, infantile diseases, lesions, leukemia, lupus, Lyme disease, parasites, dental plaque,

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rheumatism, ringworm shingles, skin cancer, staph and strep infections, stomach flu, thyroid conditions, tonsillitis, toxemia, stomach ulcers and whooping cough; (2) kills the HIV virus and can be used as an antibiotic for all acquired diseases of active AIDS; (3) is superior to antibiotics in killing disease-causing organisms and the treatment of burns; (4) protects and strengthens the immune system; (5) can safely be used on open wounds, sprayed into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes; (6) has no side effects, even at double or triple the normal dose of 250 ppm, and is safe for children and pregnant and nursing women; and (7) aids the growth and health of the developing fetus and eases delivery and recovery.

Although we deny the FTC's allegations, we have agreed to send this letter and offer you a refund. In order to receive a refund, please complete the enclosed form and return it to Kris Pletschke at 11355 SW 14th Street, Beaverton, OR 97005.

Kris Pletschke**REFUND REQUEST**

The undersigned hereby requests a refund for the purchase of *Colloidal Silver*.

Full Name (Please Print):

Address:

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Purchase Price, including shipping, handling and taxes:

It is not necessary to include proof of purchase, such as credit card statements, canceled checks, or receipts, but doing so may expedite your refund request in the event of a dispute concerning the amount of your refund.

Date: _____

Signature of Consumer:

Decision and Order

ATTACHMENT C

[ADDRESS AND TELEPHONE NUMBER OF THE
DECLARANT]

[DATE]

Kris Pletschke
11355 SW 14th Street
Beaverton, OR 97005

Dear Mr. Pletschke

I make the following Declaration of Purchase.

On or about **[DATE]**, I purchased **[NUMBER OF PACKAGES]**
of **[PRODUCT(S)]** at **[PRICE PER UNIT]**. Moreover, I
incurred **[DOLLAR AMOUNT]** in shipping and handling
charges and taxes as a result of this purchase(s). I request a refund
for **[TOTAL DOLLAR AMOUNT FOR PRODUCT(S),
SHIPPING AND HANDLING, AND TAXES]**.

I declare under penalty of perjury that the foregoing is true and
correct.

[DECLARANT'S FULL NAME]

[DECLARANT'S SIGNATURE]

[DATE]

Analysis

Analysis of Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement to a consent order from Kris A Pletschke, d/b/a/ Raw Health ("respondent"), and has issued a Complaint and the Decision and Order ("Order") contained in the Consent Agreement. Respondent marketed "Colloidal Silver," a dietary supplement allegedly containing submicroscopic particles of silver that was intended to be taken orally and in other manners for the cure and treatment of more than 650 diseases.

The Commission's complaint charges that respondent made false claims that his Colloidal Silver product (1) is effective in treating or curing 650 diseases; (2) eliminates all pathogens in the human body in six minutes or less; and (3) has been medically proven to kill every destructive bacterial, viral and fungal organism in the body, including anthrax, Ebola, Hunta, and "flesh-eating bacteria." The Commission's complaint also charges that respondent failed to have a reasonable basis for claims he made that his Colloidal Silver product (1) is effective in treating 650 diseases and health-related conditions, including AIDS, allergies, anthrax, arthritis, blood poisoning, boils, wounds of the cornea, chronic fatigue, cerebral spinal meningitis, candida, cholera, colitis, cystitis, dental plaque, diabetes, diphtheria, dysentery, enlarged prostate, gonorrhea, herpes, hepatitis, infantile diseases, lesions, leukemia, lupus, Lyme disease, parasites, rheumatism, ringworm shingles, skin cancer, staph and strep infections, stomach flu, thyroid conditions, tonsillitis, toxemia, stomach ulcers and whooping cough; (2) kills the HIV virus and can be used as an antibiotic for all acquired diseases of active AIDS; (3) is superior to antibiotics in killing disease-causing organisms and the treatment of burns; (4) protects and strengthens the immune system; (5) can safely be used on open wounds, sprayed into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes; (6) has no side effects, even at double or triple the normal dose of 260 ppm, and is safe for children and pregnant and nursing women; and (7) aids the growth and health of the developing fetus and eases delivery and recovery.

Analysis

Part I of the consent order prohibits respondent from misrepresenting any claims that Colloidal Silver or any food, dietary supplement, drug, device, or health-related service or program has been medically proven to kill disease-causing organisms or any number of infections in the body. Part II of the order requires competent and reliable scientific evidence to substantiate representations that Colloidal Silver or any covered product (1) is effective in treating 650 diseases and health-related conditions, including AIDS, allergies, anthrax, arthritis, blood poisoning, boils, wounds of the cornea, chronic fatigue, cerebral spinal meningitis, candida, cholera, colitis, cystitis, dental plaque, diabetes, diphtheria, dysentery, enlarged prostate, gonorrhea, herpes, hepatitis, infantile diseases, lesions, leukemia, lupus, Lyme disease, parasites, rheumatism, ringworm shingles, skin cancer, staph and strep infections, stomach flu, thyroid conditions, tonsillitis, toxemia, stomach ulcers and whooping cough; (2) kills the HIV virus and can be used as an antibiotic for all acquired diseases of active AIDS; (3) is superior to antibiotics in killing disease-causing organisms and the treatment of burns; (4) protects and strengthens the immune system; (5) can safely be used on open wounds, sprayed into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes; (6) has no side effects, even at double or triple the normal dose of 260 ppm, and is safe for children and pregnant and nursing women; (7) aids the growth or health of the developing fetus or eases delivery or recovery; (8) is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or (9) has any health, performance, safety, or efficacy benefits.

Part III of the order prohibits respondent from misrepresenting, including by means of metatags, the existence, contents or interpretation of any test, study, or research. Part IV of the order permits respondent to make certain claims for drugs or dietary supplements, respectively, that are permitted in labeling under laws and/or regulations administered by the U.S. Food and Drug Administration.

Analysis

Parts V and VI of the order require respondent to offer refunds to all of his past consumers and wholesale purchasers of Colloidal Silver. Part VII requires respondent to file a sworn affidavit with the Commission concerning his compliance with the refund provisions.

The remainder of the order contains standard requirements that respondent maintain advertising and any materials relied upon as substantiation for any representation covered by substantiation requirements under the order; distribute copies of the order to certain company officials and employees; notify the Commission of any change in the business entity that may affect compliance obligations under the order; and file one or more reports detailing his compliance with the order. Part XV of the order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

This order will resolve the claims alleged in the complaint against the named respondent. It is not the Commission's intent that acceptance of this consent agreement and issuance of a decision and order will release any claims against any unnamed persons or entities associated with the conduct described in the complaint.

Effective Date of Order and Opportunity for Public Comment

The Commission issued the Complaint and the Decision and Order, and served them upon the Respondent, at the same time it accepted the Consent Agreement for public comment. As a result of this action, the Order has already become effective. In August 1999, the Commission adopted procedures to allow for immediate effectiveness of an Order prior to a public comment period. The Commission announced that it "contemplates doing so only in exceptional cases where, for example, it believes that the allegedly unlawful conduct to be prohibited threatens substantial and imminent public harm." 64 Fed. Reg. 46267 (1999).

This case is an appropriate one in which to issue a final order before receiving public comment because the complaint alleges

Analysis

that the respondent made false and unsubstantiated health and safety claims of a serious nature, and the respondent continued to make the challenged claims after signing the consent agreement. Accordingly, the Commission believes it is important to prohibit the respondent from making these claims as quickly as possible.

The Order has also been placed on the public record for 30 days for receipt of comments by interested persons, and comments received during this period will become part of the public record. Thereafter, the Commission will review the Order, and may determine, on the basis of the comments or otherwise, that the Order should be modified.¹

The Commission anticipates that the Order, as issued, will satisfactorily address the deceptive practices alleged in the Complaint. The purpose of this analysis is to invite public comment on the Order to aid the Commission in determining whether to modify the Order in any respect, and is not intended to constitute an official interpretation of the agreement and order, or to modify in any way their terms.

¹ If the Respondent does not agree to such modifications, the Commission may (1) initiate a proceeding to reopen and modify the Order in accordance with Rule 3.72(b), 16 CFR § 3.72(b), or (2) commence a new administrative proceeding by issuing an administrative complaint in accordance with Rule 3.11, 16 CFR § 3.11. *See* 16 CFR § 2.34(e)(2).

Complaint

IN THE MATTER OF

AMERICAN HOME PRODUCTS

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket 9297; File No. 9910256

Complaint, March 30, 2002--Decision, April 2, 2002

This consent order addresses allegations in the administrative complaint issued earlier that Respondent American Home Products Corporation, which develops and markets brand name and generic drugs, as well as over-the-counter medications, unlawfully agreed with Schering-Plough Corporation to delay selling its generic version of Schering's K-Dur 20 – an extended-release micro-encapsulated potassium chloride product, marketed as a brand name drug and used to treat patients who suffer from insufficient levels of potassium, which can lead to serious cardiac problems – in exchange for payments from Schering. The order, among other things, prohibits the respondent from entering into agreements to resolve patent infringement disputes wherein a New Drug Application holder makes payments or otherwise transfers something of value to an Abbreviated New Drug Application filer and (2) the ANDA filer agrees not to market its product for some period of time, except under certain limited circumstances. The order also prohibits the respondent from entering into agreements between an NDA holder and an ANDA filer in which the ANDA filer agrees not to develop or market a generic drug product that is not the subject of a claim of patent infringement. In addition, the order prohibits the respondent from entering into agreements that involve payment to an ANDA filer, in which the ANDA filer agrees not to enter the market for a period of time, but the patent infringement litigation at issue continues.

Participants

For the Commission: *Karen G. Bokat, Phillip M. Eisenstat, David R. Pender, Susan Creighton, and Andrea L. Foster.*

For the Respondent: *Michael N. Sohn and Cathy Hoffman, Arnold & Porter.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in the agency by said