

Inspections, Compliance, Enforcement, and Criminal Investigations

Legal Gear 08-Mar-06



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, MD 20740

March 8, 2006

WARNING LETTER

By facsimile

Legal Gear
815 N. Second Street, Suite #109
Brighton, MI 48116

Dear Sir/Madam:

This letter relates to your product Methyl 1-P®, containing the synthetic steroids 6-alpha-methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone. The product label and your Internet website at <http://www.legalear.com> list 6-alpha-methyl-etiocholene-3,17-dione as an ingredient, and analysis of this product revealed that it is also contains another steroid not declared as an ingredient, 17a-hydroxyprogesterone. The product label and your website state that this product contains an "anabolic agent." Further, your website includes statements about this product such as the following:

- "[E]ven more potent at building muscle than many illegal anabolics!"
- "[T]he only legal choice for people wanting to build serious mass and gain massive strength"

The product label and your website represent this product as a dietary supplement. However, the product cannot be a dietary supplement because the active ingredients used in the product, 6-alpha-methyl-etiocholene-3, 17-dione

and 17a-hydroxyprogesterone, are not vitamins, mineral, amino acids, herbs, or other botanicals, or dietary substances for use by man to supplement the diet by increasing the total dietary intake, nor are they concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient described above. Rather, both of these ingredients are synthetic steroids. Consequently, 6-alpha-methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone are not "dietary ingredients" as defined in Section 201(ff)(1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 USC 321(ff)(1)], and your product is not a dietary supplement because it does not contain a dietary ingredient.

Under Section 201(g)(1) of the Act [21 USC 321(g)(1)(C)], products that are intended to affect the structure or function of the body are defined as drugs. The description of your product as "anabolic" on your product label and website, together with the other claims quoted above, establish that your product is intended to affect the structure or function of the body by building muscle and increasing strength. Based on these claims, FDA considers Methyl 1-P® to be a drug.

Moreover, your product is also a new drug under Section 201(p) of the Act [21 USC 321(p)] because this product is not generally recognized as a safe and effective for the uses claimed in its labeling. Under Section 505(a) of the Act [21 USC 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505(a) of the Act. Section 301(d) of the Act [21 USC 331(d)] prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 505.

You should also be aware that anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These includes liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations of the Act described above are not intended to be an all-inclusive list of violation concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations and any similar violations associated with other other products you market that contain 6-alpha-methyl-etiocholene-3, 17-dione or 17a-hydroxyprogesterone. Failure to promptly correct the violations may result in FDA enforcement action without further action. The Act provides for seizure of illegal products, injunction against the manufacturers and distributors of illegal products, and criminal sanctions against persons responsible for causing violations of the Act [21 U.S.C. 332,333, and 334].

Please notify this office in writing, within fifteen working days of receipt of this letter, as to the specific steps you have taken to correct the violations described above, and an explanation of each step taken to assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented. In your reply, please described your intent with respect to products that have already been distributed.

Your reply should be sent to the attention of Jennifer Thomas, Compliance Officer, at the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, Rockville, MD 20740.

Sincerely,

/S/

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

Inspections, Compliance, Enforcement, and Criminal Investigations

Anabolic Resources LLC 08-Mar-06



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, MD 20740

MARCH 8, 2006

WARNING LETTER

Mr. Mike Keplinger
Anabolic Resources LLC
170 S William Dillard Drive
Gilbert, AZ 85233

Dear Mr. Keplinger:

This letter relates to your product Anabolic Xtreme Superdrol, containing the synthetic steroid methasteron. The product label and your Internet website, <http://www.anabolicx.com>, state that this product is "anabolic" and list methasteron as an ingredient. Further, your website includes statements about this product such as the following:

- "Many people have packed on pounds of lean mass and increased their strength while using this potent supplement"
- "The average user will gain between 6-10 pounds in as little as three weeks."

Although Anabolic Xtreme Superdrol is not currently available on your website, where it is marked "Discontinued," it is still being distributed in interstate commerce with a label that lists your firm name and website. The product label and your website represent this product as a dietary supplement. However, the product cannot be a dietary supplement because the active ingredient used in the product, methasteron, is not a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, nor is it a concentrate, metabolite, constituent, extract, or combination of any dietary ingredient described above. Rather, it is a

synthetic steroid. Consequently, methasteron is not a "dietary ingredient" as defined in Section 201(ff)(1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 USC 321(ff)(1)], and your product is not a dietary supplement because it does not contain a dietary ingredient.

Under Section 201(g)(1)(C) of the Act [21 USC 321(g)(1)(C)], products that are intended to affect the structure or function of the body are defined as drugs. The description of your product as "anabolic" on your product label and website, together with the other claims quoted above, establish that your product is intended to affect the structure or function of the body by building muscle, increasing strength, and inducing weight gain. Based on these claims, FDA considers Anabolic Xtreme Superdrol to be a drug.

Moreover, your product is also a new drug under Section 201(p) of the Act [21 USC 321(p)] because this product is not generally recognized as safe and effective for the uses claimed in its labeling. Under Section 505(a) of the Act [21 USC 355 (a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505 (a) of the Act. Section 301(d) of the Act [21 USC 331(d)] prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 505.

You should also be aware that anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations of the Act described above are not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations and any similar violations associated with other products you market that contain methasteron. Failure to promptly correct the violations may result in FDA enforcement action without further notice. The Act provides for seizure of illegal products, injunction against the manufacturers and distributors of illegal products, and criminal sanctions against persons responsible for causing violations of the Act [21 U.S.C. 332, 333, and 341].

Please notify this office in writing, within fifteen working days of receipt of this letter, as to the specific steps you have taken to correct the violations described above, and an explanation of each step taken to assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented. In your reply, please describe your intent with respect to products

that have already been distributed.

Your reply should be sent to the attention of Jennifer Thomas, Compliance Officer, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740.

Sincerely,

/S/

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition.

Inspections, Compliance, Enforcement, and Criminal Investigations

Supplementstogo.com, LLC 08-Mar-06



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, MD 20740

March 8, 2006

WARNING LETTER

By facsimile

Mr. Joe Godar
Supplementstogo.com, LLC
5130 Crookshank Road
Cincinnati, OH 45238

Dear Mr. Godar:

This letter relates to your firm's marketing of the product Anabolic Xtreme Superdrol, containing the synthetic steroid methasteron. The product label and your Internet website, <http://www.supplementstogo.com>, state that this product is "anabolic" and list methasteron as an ingredient. Further, your website includes statements about this product such as the following:

- "Many people have packed on pounds of lean mass and increased their strength while using this potent supplement"
- "The average user will gain between 6-10 pounds in as little as three weeks."

The product label and your website, from which this product may be ordered, represent this product as a dietary supplement. However, the product cannot be a dietary supplement because the active ingredient used in the product, methasteron, is not a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, nor is it a concentrate, metabolite, constituent, extract or combination of any dietary ingredient described above. Rather, it is a synthetic steroid. Consequently, methasteron is not a "dietary ingredient" as defined in

Section 201(ff) (1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 USC 321(ff)(1)], and your product is not a dietary supplement because it does not contain a dietary ingredient.

Under Section 201(g)(1)(C) of the Act [21 USC 321(g)(1)(C)], products that are intended to affect the structure or function of the body are defined as drugs. The description of your product as "anabolic" on your product label and website, together with the other claims quoted above, establish that your product is intended to affect the structure or function of the body by building muscle, increasing strength, and inducing weight gain. Based on these claims, FDA considers Anabolic Xtreme Superdrol to be a drug.

Moreover, your product is also a new drug under Section 201(p) of the Act [21 USC 321(p)] because this product is not generally recognized as safe and effective for the uses claimed in its labeling. Under Section 505(a) of the Act [21 USC 355 (a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505 (a) of the Act. Section 301(d) of the Act [21 USC 331(d)] prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 505.

You should also be aware that anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations of the Act described above are not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations and any similar violations associated with other products you market that contain methasteron. Failure to promptly correct the violations may result in FDA enforcement action without further notice. The Act provides for seizure of illegal products, injunction against the manufacturers and distributors of illegal products, and criminal sanctions against persons responsible for causing violations of the Act [21 U.S.C. 332, 333, and 334].

Please notify this office in writing, within fifteen working days of receipt of this letter, as to the specific steps you have taken to correct the violations described above, and an explanation of each step taken to correct the violations described above, and an explanation of each steps to ensure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented. In your reply, please describe your intent with respect to products

that have already been distributed.

Your reply should be sent to the attention of Jennifer Thomas, Compliance Officer, at the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740.

Sincerely,

/S/

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

Inspections, Compliance, Enforcement, and Criminal Investigations

Affordable Supplements 08-Mar-06



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, MD 20740

March 8, 2006

WARNING LETTER

By facsimile

Affordable Supplements
7011 West Central, Suite 117
Wichita, KS 67212

455 Whitney Street
Northborough, MA 01532

Dear Sir/Madam:

This letter relates to your firm's marketing of the product Legal Gear Methyl 1-P®, containing the synthetic steroids 6-alpha-methyl-etiocholene-3,17-dione and 17ahydroxyprogesterone. The product label and your Internet website at <http://www.affordablesupplements.com> list 6-alpha-methyl-etiocholene-3,17-dione as an ingredient, and analysis of this product revealed that it also contains another steroid not declared as an ingredient, 17a-hydroxyprogesterone. The product label and your website state that this product contains an "anabolic agent." Further, your website includes statements about this product such as the following:

- "[C]apable of building huge muscle and without any side effects"
- "[S]olid gains in mass with limited side effects."
- [T]he only legal choice for people wanting to build serious mass and gain

massive strength."

The product label and your website, from which this product may be ordered, represent this product as a dietary supplement. However, the product cannot be a dietary supplement because the active ingredients used in the product, 6-alpha-methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone, are not vitamins, minerals, amino acids, herbs or other botanicals, or dietary substances for uses by man to supplement the diet by increasing the total dietary intake, nor are they concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient described above. Rather, both of these ingredients are synthetic steroids. Consequently, 6-alpha-methyl-etiocholene-3,17--dione and 17a-hydroxyprogesterone are not "dietary ingredients" as defined in Section 201 (ff) (1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 USC 321(ff)(1)], and your product is not a dietary supplement because it does not contain a dietary ingredient.

Under Section 201(g)(1)(C) of the Act [21 USC 321(g)(1)(C)], products that are intended to affect the structure or function of the body are defined as drugs. The description of your product as "anabolic" on your product label and website, together with the other claims quoted above, establish that your product is intended to affect the structure or function of the body by building muscle and increasing strength. Based on these claims, FDA considers Legal Gear Methyl-1-P® to be a drug.

Moreover, your product is also a new drug under Section 201(p) of the Act [21 USC 321(p)] because this product is not generally recognized as safe and effective for the uses claimed in its labeling. Under Section 505(a) of the Act [21 USC 355 (a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505 (a) of the Act. Section 301(d) of the Act [21 USC 331(d)] prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 505.

You should also be aware that anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations of the Act described above are not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations and any similar violations associated with other products you market that contain 6-alpha-methyl-

etiocholene-3,17-dione or 17a-hydroxyprogesterone. Failure to promptly correct the violations may result in FDA enforcement action without further notice. The Act provides for seizure of illegal products, injunction against the manufacturers and distributors of illegal products, and criminal sanctions against persons responsible for causing violations of the Act [21 U.S.C. 332, 333, and 334].

Please notify this office in writing, within fifteen working days of receipt of this letter, as to the specific steps you have taken to correct the violations described above, and an explanation of each step taken to assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented. In your reply, please describe your intent with respect to products that have already been distributed.

Your reply should be sent to the attention of Jennifer Thomas, Compliance Officer, at the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, Rockville, MD 20740.

Sincerely,

/S/

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

United States of America,	)	
	)	
Plaintiff,	)	No. 2:08-cv-11395
	)	
v.	)	Honorable NANCY G. EDMUNDS
	)	
605 cases, more or less,	)	Magistrate DONALD L. SCHEER
of an article of food, each case containing	)	
12/135 Capsule Bottles, et al.,	)	
Bottles, et al.,	)	
	)	
Defendants.	)	

AMENDED COMPLAINT FOR FORFEITURE

To the Honorable Judge of the United States District Court for the Eastern District of Michigan.

Now comes the United States of America by Terrence Berg, Acting United States Attorney for the Eastern District of Michigan, and shows to the Court:

NATURE OF THE ACTION

1. That this complaint is filed by the United States of America, and requests seizure and condemnation of articles of food, as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. §§ 301 *et seq.*

2. That there are at Brighton, Michigan, in the possession of LG Sciences, 6150 Whitmore Lake Road, or elsewhere within the jurisdiction of this Court, articles of food, as described in the caption, which articles were shipped in interstate commerce from outside the State of Michigan.

JURISDICTION AND VENUE

3. That plaintiff brings this action *in rem* to condemn and forfeit the defendant property. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provides the court with jurisdiction over seizures brought under the Act.

4. That this Court has *in rem* jurisdiction over the articles because they are located in the Eastern District of Michigan. An arrest warrant *in rem* is not necessary upon the filing of this amended complaint, however, as the articles at issue remain subject to the judicial restraining order issued by this Court on April 2, 2008. *See* Supplemental Rule G(3)(b)(iii).

5. That venue is proper in this district pursuant to 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1) because the articles are located at LG Sciences, 6150 Whitmore Lake Road, Brighton, Michigan.

BASIS FOR FORFEITURE

6. The articles are labeled as dietary supplements and contain the substance 1,4,6-etioallocholan-dione, which is identified on the label as a dietary ingredient; however, this substance does not meet the statutory definition of a dietary ingredient under the Act, 21 U.S.C. § 321(ff), in that it is not a vitamin, mineral, herb or other botanical, amino acid, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, nor is it a concentrate, metabolite, constituent, extract, or combination of any dietary ingredient described above.

7. That the articles are adulterated while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C., as follows:

a. The articles are adulterated under § 342(a)(2)(C), in that they (all lots) contain 1,4,6-etioallocholan-dione, an unapproved food additive which is unsafe within the meaning of 21 U.S.C. § 348. Any substance, other than a dietary ingredient, which is intentionally added to a dietary supplement must be used in accordance with a food additive regulation approving the substance for that use, unless the substance is generally recognized as safe among experts qualified by scientific training and experience to evaluate its safety under the conditions of intended use, or is otherwise exempt from the food additive definition in 21 U.S.C. § 321(s). The substance 1,4,6-etioallocholan-dione is not generally recognized as safe, nor is it exempt from the food additive definition in 21 U.S.C. § 321(s). Therefore, it is not approved for use as a food additive.

b. In the alternative, should the Court find that 1,4,6-etioallocholan-dione is a dietary ingredient under U.S.C. § 321(ff) and not an unsafe food additive, the articles are adulterated under § 342(f)(1)(B), in that they (all lots) contain this substance. The substance 1,4,6-etioallocholan-dione is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

c. The articles called "Formadrol Extreme XL" are adulterated under § 342(f)(1)(B) in that they are labeled as a dietary supplement and contains 4-etioallocholen-3,6,17-trione. This substance is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

8. That by reason of the foregoing, the articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation.

FACTS

9. The U.S. Food and Drug Administration (FDA) issued a Warning Letter to Legal Gear, Brighton, Michigan, on March 8, 2006. The letter stated that the firm's product, Methyl 1-P®, contained the synthetic steroids 6-alpha methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone. The product was labeled as a dietary supplement, however, the ingredients were not dietary ingredients. The product did not contain any dietary ingredients and so did not meet the definition of a dietary supplement. The Warning Letter stated that, because the product made claims to affect the structure or function of the body, it was a drug. Because the product was not approved for the uses set out in the labeling, it was a new drug. Legal Gear was advised that continued distribution of the drug, for which there is no approved application, is a violation of the law. The firm discontinued distribution of Methyl 1-P® and recalled the product from the marketplace. The firm was also advised in the Warning Letter that it was responsible for ensuring that all products it markets comply with the Act and its implementing regulations.

10. Legal Gear is an alternative name for DOX, LLC, Brighton, Michigan. The company also uses the name LG Sciences. In March 2006, Eric Marchewitz was the President and Managing Member and he signed the firm's recall letters for Methyl 1-P®.

11. LG Sciences, LLC was organized on June 23, 2006. The Manager of LG Sciences, LLC is Eric Marchewitz.

12. In July 2006, Legal Gear sold its inventory and formulations to a newly created company, LG Sciences, LLC, Brighton, Michigan, at the same address.

13. Legal Gear's web site, www.legalgear.com, redirects the visitor to www.lgsciences.com.

14. FDA conducted a follow-up investigation to the March 2006 Warning Letter to determine if the firm was operating in compliance with the Act. The FDA Investigator confirmed that Methyl 1-P® is no longer being distributed by either Legal Gear or LG Sciences, LLC.

15. Currently, LG Sciences is distributing at least three products labeled as dietary supplements with a component, 1,4,6-etioallocholan-dione, which to FDA's knowledge is not a dietary ingredient. If 1,4,6-etioallocholan-dione is a dietary ingredient, however, it is a new dietary ingredient. The three products known to contain 1,4,6-etioallocholan-dione are Methyl 1-D XL, Methyl 1-D, and Formadrol Extreme XL capsules. In addition, the product Formadrol Extreme XL is labeled to contain 4-etioallocholen-3,6,17-trione, which is a new dietary ingredient.

16. The substance 1,4,6-etioallocholan-dione is also known as "1,4,6-androstatrien-3,17-dione" or "ATD." ATD is used in body building products to control estrogen synthesis.

17. During the inspection conducted on October 11-30, 2007, FDA sampled the lots on hand at LG Sciences, of Methyl 1-D XL, Methyl 1-D, and Formadrol Extreme XL capsules. Analyses by FDA's Forensic Chemistry Center confirmed the presence of ATD in all three

products. FDA's analyses also confirmed the presence in the Formadrol Extreme XL product of 4-etioallocholen-3,6,17-trione, a substance also known as "6-OXO."

18. Despite the warning provided in the March 2006 Warning Letter of the need to ensure that all products marketed by the firm comply with the Act and its implementing regulations, the firm has continued to market products in violation of the Act.

We request that process issue against the articles; that all persons having any interest in the articles be cited to appear herein and answer the allegations in the complaint; that this Court decree the condemnation of the articles and grant plaintiff the costs of this proceeding against the claimant of the articles; that the articles be disposed of as this Court may direct pursuant to the provisions of the Act; and that plaintiff have such other and further relief as the case may require.

Respectfully submitted,

TERRENCE BERG
Acting United States Attorney

/s/ Carolyn Bell Harbin
CAROLYN BELL HARBIN
Assistant United States Attorney
211 W. Fort Street, Ste. 20001
Detroit, MI 48334
(313) 226-9114
Carolyn.Bell-Harbin@usdoj.gov
(P27350)

/s/ John W.M. Claud
JOHN W.M. CLAUD
Trial Attorney
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OF COUNSEL:

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Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel,
Litigation

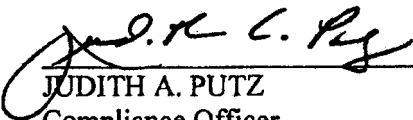
JENNIFER ZACHARY
Associate Chief Counsel
United States Department of
Health and Human Services
Office of the General Counsel
5600 Fishers Lane, GCF-1
Rockville, MD 20857
(301) 827-9572

VERIFICATION

I, JUDITH A. PUTZ, Compliance Officer for the Food and Drug Administration, U.S. Department of Health and Human Services, have read the foregoing Amended Complaint for Forfeiture in this action and state that its contents are true and correct to the best of my knowledge, information, and belief.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

This 6th day of November, 2008.



JUDITH A. PUTZ
Compliance Officer
Food and Drug Administration

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

United States of America,	)	
	)	
Plaintiff,	)	No. 2:08-cv-11395
	)	
v.	)	Honorable NANCY G. EDMUNDS
	)	
605 cases, more or less,	)	Magistrate DONALD L. SCHEER
of an article of food, each case containing	)	
12/135 Capsule Bottles, et al.,	)	
Bottles, et al.,	)	
	)	
Defendants.	)	

CONSENT DECREE OF CONDEMNATION AND DESTRUCTION

On April 2, 2008, Plaintiff, the United States of America, by its undersigned attorneys, filed a Complaint for Forfeiture in this Court against the defendant articles of food ("Articles"), which alleged that the Articles are adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 334(a)(1).

On April 2, 2008, the United States Marshal for this District seized the Articles at 6150 Whitmore Lake Road, Brighton, Michigan, pursuant to the Warrant for Arrest issued by this Court. On April 11, 2008, LG Sciences, LLC ("LG Sciences"), through its attorney, intervened and filed a Verified Statement of Interest, asserting an ownership interest in the Articles. On May 8, 2008, LG Sciences answered the Complaint for Forfeiture.

On November 10, 2008, Plaintiff filed an Amended Complaint for Forfeiture ("Amended Complaint"), which alleges that the seized Articles are: (1) adulterated within the meaning of the Act, 21 U.S.C. §§ 342(f)(1)(B) and 348(a), in that all lots contain 1,4,6-etioallocholan-dione ("ATD"), which is either an unapproved food additive or a new dietary ingredient for which inadequate information exists to provide reasonable assurance that it does not present a

significant or unreasonable risk of illness or injury; (2) adulterated within the meaning of the Act, 21 U.S.C. § 342(f)(1)(B), in that the seized lots of Formadrol XL contain 4-etioallocholen-3,6,17-trione ("6-OXO"), which is a new dietary ingredient for which inadequate information exists to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury; and (3) by reason of the foregoing, the Articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C.

§ 334(a)(1). On December 12, 2008, LG Sciences answered the Amended Complaint, denying Plaintiff's allegations. LG Sciences is the sole claimant in this action.

WHEREAS LG Sciences has appeared and, before any testimony has been taken, agreed to the entry of this Consent Decree without contest, on the motion of the parties hereto, it is now

ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 334. Venue is proper in this district under 28 U.S.C. § 1395(b).
2. The Amended Complaint states a claim for relief against the Articles under the Act.
3. LG Sciences affirms that it is the sole owner of the Articles, that no other person has an interest in the Articles, and that it will indemnify and hold Plaintiff harmless should any party or parties hereafter file or seek to file a statement of interest, or to intervene in this action and obtain or defend any part of the Articles subject to this Consent Decree.
4. The Amended Complaint alleges that the Articles are adulterated.
5. LG Sciences denies those allegations in the Amended Complaint, and solely in a compromise to resolve this proceeding the Articles are to be destroyed as set forth below.
6. The Articles are therefore condemned and forfeited to the Plaintiff.

7. Pursuant to 21 U.S.C. § 334(e), LG Sciences shall pay to the United States all court costs and fees, storage, and other proper expenses to date, and such additional expenses as may hereinafter be incurred and taxed, date, as set forth in paragraph 19 of this Consent Decree.

LG Sciences shall pay these costs in full within fifteen (15) days of receiving written notice from the Food and Drug Administration ("FDA") of such costs.

8. Pursuant to 21 U.S.C. § 334(d)(1), within twenty (20) days of the entry of this Consent Decree, LG Sciences shall execute and file with the Clerk of this Court a good and sufficient penal bond with surety ("Bond") in the amount of fifty thousand dollars (\$50,000.00) in a form acceptable to the Clerk of this Court, to be applied to Lot 1 (as described in Subpart A of Paragraph 11 of this Decree) and held for application to succeeding Lots 2-26 (as described in Subparts B-C of Paragraph 11 of this Decree), payable to the United States of America, and conditioned on LG Sciences abiding by and performing all of the terms and conditions in this Consent Decree.

9. After paying the costs pursuant to paragraph 7 and posting the Bond as specified in paragraph 8, LG Sciences shall give written notice to FDA at the Detroit District Office, U.S. Food and Drug Administration, 300 River Place, Suite 5900, Detroit, Michigan 48207, that LG Sciences, at its own expense, is prepared to destroy the Articles, pursuant to 21 U.S.C. § 334(d), under the supervision of a duly authorized representative(s) of the United States Department of Health and Human Services ("FDA representative"). LG Sciences's notice shall specify the proposed time, place, and method of destruction of the Articles.

10. LG Sciences shall not commence destroying the Articles until it has received written authorization to commence with the destruction from an FDA representative. All Articles shall be destroyed at LG Sciences's expense under the supervision of an FDA representative.

LG Sciences shall pay to the United States all costs incurred in supervising the destruction of the Articles, at the rates specified in paragraph 19 of this Consent Decree.

11. Upon receiving notice from the United States Attorney for this District or FDA that LG Sciences is authorized to commence destroying the Articles, the United States Marshal for this District shall release the appropriate Lot of Articles (as described in Subparts A-C, below) to the custody of LG Sciences for the sole purpose of destroying the Articles pursuant to the destruction plan described in paragraphs 8 and 9 of this Consent Decree. The schedule for release of the Articles is as follows:

A. The Articles in Lot 1, consisting of approximately 1/26 of the Articles (by value), to be further designated by the FDA representative, shall be released to LG Sciences for the sole purpose of destroying the Articles.

B. If and only if LG Sciences complies with all of the terms of this Consent Decree with respect to Lot 1, the Articles in Lot 2, consisting of approximately a second 1/26 of the seized Articles (by value), to be further designated by the FDA representative, shall be released to LG Sciences for the sole purpose of destroying the Articles.

C. Lots 3-26, each consisting of approximately 1/26 of the seized Articles (by value), each to be further designated by the FDA representative, shall be released in succession, if and only if LG Sciences complies with all of the terms of this Consent Decree with respect to each preceding Lot (as described in Subpart B), to LG Sciences for the sole purpose of destroying the Articles.

12. LG Sciences shall at all times, until the Articles have been destroyed, retain the Articles intact for examination, inspection, or sampling by an FDA representative, and shall maintain all

records or other proof necessary to establish the identity of the Articles to the satisfaction of an FDA representative.

13. LG Sciences shall not cause the Articles or any part thereof to be disposed of in a manner contrary to the provisions of the Act, any other federal law, or the laws of any State or Territory (as defined in the Act) in which the articles are disposed. LG Sciences shall furnish duplicate copies of evidence of disposition of the articles, if requested by an FDA representative.

14. Within thirty (30) days of entry of this Consent Decree, LG Sciences shall complete the destruction of the Articles under the supervision of an FDA representative. Within fifteen (15) days of LG Sciences's completion of the destruction of the Articles, an FDA representative will send LG Sciences an invoice for the costs of supervising such destruction, and LG Sciences shall pay those costs within ten (10) days of receiving the invoice.

15. The United States Attorney for this District, upon being advised by an FDA representative that the preceding conditions of this Consent Decree have been performed, shall transmit such information to the Clerk of this Court, whereupon the Bond given in this proceeding shall be canceled and discharged.

16. If LG Sciences fails to abide by and perform all of the terms and conditions stated in this Consent Decree, then the Bond shall, on motion of Plaintiff in this proceeding, be forfeited in its entirety to Plaintiff and judgment entered in favor of Plaintiff.

17. If LG Sciences breaches any term or condition of this Consent Decree, then LG Sciences shall, at its own expense, immediately return the Articles to the United States Marshal for this District or otherwise dispose of them pursuant to an order of this Court. Following return of the seized articles, the United States Marshal shall destroy the articles and make due return to this Court regarding their disposition. In the event that return of the Articles becomes necessary

pursuant to this paragraph, LG Sciences shall be responsible for all costs of storage and disposition that are incurred by Plaintiff. LG Sciences shall pay such costs within ten (10) days of receiving written notice from an FDA representative of these expenses.

18. If LG Sciences does not avail itself of the opportunity to repossess and destroy the Articles in the manner provided in this Consent Decree, the United States Marshal for this District shall retain custody of the seized articles and destroy them, and make due return to this Court regarding their disposition. LG Sciences shall pay all costs associated with storage and disposition of the seized articles incurred by Plaintiff. LG Sciences shall pay such costs within ten (10) days of receiving written notice from an FDA representative of these expenses.

19. LG Sciences shall reimburse Plaintiff for the costs of supervising LG Sciences's compliance with the terms of this Consent Decree, including all inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Consent Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Consent Decree is signed by the parties, these rates are: \$81.61 per hour and fraction thereof per representative for inspection work; \$97.81 per hour or fraction thereof per representative for analytical or review work; \$0.585 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

20. LG Sciences shall abide by the decisions of FDA regarding destruction of the Articles, which shall be final. All decisions specified in this Consent Decree shall be vested in the

discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by a Court of any FDA decision rendered pursuant to this Consent Decree shall be conducted without any discovery by either party and shall be based exclusively upon the written record that was before FDA at the time the decision was made.

21. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to the proper disposition of this proceeding.

SO ORDERED:

s/Nancy G. Edmunds
Nancy G. Edmunds
United States District Judge

Dated: May 11, 2009

I hereby certify that a copy of the foregoing document was served upon the parties and/or counsel of record on May 11, 2009, by electronic and/or ordinary mail.

s/Carol A. Hemeyer
Case Manager

We hereby consent to the foregoing Decree.

For Defendants:

LG SCIENCES, LLC

s/ Warren D. Hopper
WARREN D. HOPPER,
Its: Authorized Representative

s/ Thomas W. Cranmer
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Miller Canfield Paddock and Stone, PLLC
840 W. Long Lake Road
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(P25252)

For Plaintiff:

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United States Attorney

s/ Carolyn Bell Harbin
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s/ John W.M. Claud
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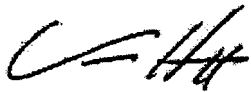
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United States Department of
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Office of the General Counsel
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For Defendants:

LG SCIENCES, LLC



s/ Warren D. Hopper
WARREN D. HOPPER,
Its: Authorized Representative

s/ Tomas W. Cranmer
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s/ Carolyn Bell Harbin
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Associate Chief Counsel

About FDA

MOU 225-74-8013

Memorandum of Understanding
Between
The Drug Enforcement Administration
and
The Food and Drug Administration

Purpose:

To outline the working arrangements for the operation and activities of the DEA/FDA Liaison Staff established for dealing with related objectives in carrying out DEA and FDA responsibilities under the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act.

I. Objectives and Structure.

The Drug Enforcement Administration and the Food and Drug Administration have established liaison staffs for dealing with related objectives in carrying out their responsibilities under the Controlled Substances Act and the Federal Food, Drug and Cosmetic Act. This Memorandum outlines the working arrangements being followed in the interest of the public so that each agency will discharge its responsibilities as effectively as possible.

The DEA/FDA Liaison Staffs will serve as a focal point for interagency coordinative management of investigative, consultant, scientific, compliance, and legal efforts, involving controlled substances or substances which are being investigated which may be controlled. The Liaison Staffs will also serve in assisting the Administrator and the Commissioner in the development and evaluation of policy.

DEA and FDA shall have the following type of representation on the liaison staff:

- a. Liaison Officer,
- b. Representative from legal office,
- c. Compliance representative,

d. Science representative,

Other personnel may attend meetings on an as-needed basis.

II. Name and Address of Participating Agencies.

Drug Enforcement Administration
Department of Justice
Washington, DC 20537.

Food and Drug Administration
Department of Health, Education, and Welfare
5600 Fishers Lane
Rockville, MD 20857

III. Liaison Officers.

A. For DEA:

Mr. Ernest A. Carabillo, Jr.
Chief
Special Programs Division
Drug Enforcement Administration
14th and I St. N.W.
Washington, DC 20537
(202) 382-4344.

B. For FDA:

Mr. Thomas W. Brown
Director
Compliance Coordination and Policy Staff (HFC-13)
Office of the Associate Commissioner for Compliance
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-3470.

IV. Operations.

A. Meetings will be held every 2 months on the second Tuesday of the month. The Liaison Officers may reschedule the meeting or convene additional meetings as

necessary. The host agency will prepare the minutes of meetings, which will be circulated to staff members by the Liaison Officer.

B. The Liaison Staff will limit its discussions to substantive matters in the area of controlled substances involving FDA (not HEW) and DEA.

C. Unresolved policy matters and problems will be referred for discussion at the periodic liaison meetings between the Administrator and the Commissioner.

D. Liaison Staff activities between agencies will be coordinated through the Offices of the Agency's Liaison Officer.

E. Important regulatory developments in both agencies will be promptly communicated to the Agency's Liaison Officer. Regular and frequent exchange of scientific, planning, and regulatory information should take place between officials and professional staffs.

F. The staff shall coordinate efforts to facilitate exchange of pertinent information necessary to controlled substances decisions.

G. The staff shall establish means to clarify and facilitate operating procedures necessary for controlled substances decisions, including, but not limited to, the following interagency cooperative efforts:

- i. Transmittal of and access to necessary documents.
- ii. Access to and knowledge of abuse information.
- iii. Staff level working groups and informal exchanges between such groups.
- iv. Location and production of expert witnesses.
- v. A unified policy concerning publicity releases.
- vi. Procedures to avoid duplication of efforts.

H. The agencies shall informally notify each other in advance of formal proposals to schedule drugs. Additionally, the agencies shall when possible, informally transmit data supporting scheduling decisions in advance of a formal transmittal.

V. Period of Agreement.

This agreement, when accepted by both parties, will have an indefinite period of performance, and may be modified by mutual consent of both parties or may be terminated by either party upon a thirty (30) day advance written notice to the other.

VI. Authority.

This agreement is entered into under the authority of the Economy Act approved June 30, 1932, as amended, 31 U.S.C. 686.

**Approved and Accepted
for the Drug Enforcement
Administration**

Signed by: Frederick M. Garfield
Director of Research and Technology

Date: July 1, 1974

**Approved and Accepted
for the Food and Drug
Administration**

Signed by: Sam D. Fine
Associate Commissioner for Compliance

Date: June 21, 1974

About FDA

MOU 225-76-3009

Memorandum of Understanding
Between
The Drug Enforcement Administration

and

The Food and Drug Administration

I. Purpose

This Memorandum of Understanding outlines the working arrangements between the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) regarding the approval or denial procedures for narcotic treatment programs (hereinafter referred to as treatment programs) and the cooperative efforts of both agencies in any denial or revocation of approval by FDA, or denial or revocation of registration by DEA initiated against these treatment programs. Treatment programs under this agreement include all programs that use any narcotic drug for the treatment of narcotic addiction.

II. Background.

The methadone regulation in Section 310.505 (21 CFR 291.505)* requires that prior approval by FDA be obtained before a treatment program may receive shipments of methadone. Before FDA may give such approval, it must consult with DEA to determine if the applicant is in compliance with the Controlled Substances Act of 1970 (CSA) and the Narcotic Addict Treatment Act (NATA) of 1974. Prior approval of the State authority is also required, except programs wholly operated by an agency of the U.S. Government.

* Recodified to 21 CFR 310.505.

The NATA of 1974 amended the CSA by requiring that all treatment programs appropriately register with DEA. DEA may not register an applicant without consulting FDA in order to determine if the program meets the medical standards established by the Secretary of Health, Education, and Welfare.

Both agencies have the authority to deny or revoke approval of a treatment program independently of each other, or at the recommendation of the other agency or a State authority, for violation of laws or regulations governing the operations of such programs.

DEA and FDA will continue to work in close cooperation to prevent treatment programs from beginning operations without the required approvals of both agencies, to coordinate any denial or revocation proceedings, and to provide for the disposition of the narcotics if a program's approval or registration is revoked.

III. Substance of Agreement.

a. Each agency shall obtain prior approval of the other before a new application for a treatment program is approved by FDA or registered by DEA. Before FDA may give approval, prior approval by the appropriate State authority is necessary, except in the case of a program wholly operated by the U.S. Government.

b. The agencies shall notify each other of any denial or revocation of approval or registration of treatment programs when such action is initiated and shall keep each other informed of the outcome of such action.

c. Investigations of treatment programs by either agency that reveal suspected violations of the regulations promulgated by the other agency shall be promptly report to that agency.

d. When one agency recommends denial or revocation of approval or registration to the other, the recommending agency shall provide the other agency with all necessary reports, documents, and testimony for successful completion of the action.

e. Both agencies shall cooperate with each other in terminating illegally operating programs and in seizing or accepting surrender of the program's drug supply, as

well as the supplies of other programs terminated for any reason.

f. FDA shall obtain DEA approval prior to approving treatment program requests for:

1. Alternate dispensing sites;
2. Alternate methods of distribution;
3. Exceptions that involve storage of methadone at locations not approved for that purpose by either FDA or DEA, e.g., jail facilities or wholesalers who only store methadone for a program;
4. Establishment of medication units.

g. FDA shall consult with DEA before approving program-wide, as opposed to individual patient, requests for additional take-home medication not provided for by the regulation.

h. The agencies shall hold periodic meetings to discuss resolution of procedural problems related to mutual enforcement activities.

i. In the forum of the Federal Methadone Treatment Policy Review Board (composed of designated representatives from the Drug Enforcement Administration, Food and Drug Administration, National Institute on Drug Abuse, and the Veterans Administration) DEA and FDA will discuss with each other, and other members of the Board, any proposed new regulations, regulation changes, or any significant interpretative modification with regard to treatment programs that will impact on the other agency.

IV. Liaison Officers.

For DEA:

Mr. Ronald W. Buzzeo
Chief
Regulatory Investigations Section
Compliance Investigation Division
1405 "I" St. N.W.
Washington, DC 20537

(202) 382-4217.

For FDA:

Mr. Buddy F. Stonecipher
Director
Div. of Methadone Monitoring (HFD-340) Bureau of Drugs
5600 Fishers Lane
Rockville, Md. 20857
(301) 443-3414.

V. Period of Agreement.

When accepted by both agencies, the agreement will have an effective period of performance from the date of signature with no expiration date. It may be modified by mutual consent of both parties or may be terminated by either party upon thirty (30) days advance written notice to the other.

At such time as the Secretary delegates authority and responsibility pursuant to the Narcotic Addict Treatment Act of 1974, this agreement will be amended to reflect any changes which may be appropriate.

Effective date. This Memorandum of Understanding became effective on May 27, 1976.

Approved and Accepted for the Drug Enforcement Administration

Signed by: Peter B. Bensinger
Administrator
Drug Enforcement Administration

Date: May 27, 1976

Approved and Accepted for the Food and Drug Administration

Signed by: A.M. Schmidt
Commissioner

Date: May 20, 1976

Approved and Accepted for the Food and Drug Administration

Signed by: Sam D. Fine
Associate Commissioner for Compliance

Date: July 2, 1976



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

February 9, 1981

Office of the General Counsel
Food and Drug Division
Rockville, MD 20855

MEMORANDUM

TO: Acting Commissioner of Food and Drugs *MW*
Director, National Institute on Drug Abuse
Administrator, Drug Enforcement Administration

FROM: Joseph A. Levitt, Chairman
Interagency Committee on Drug Control

SUBJECT: Committee Charter

Please find attached a copy of the proposed Charter for the Interagency Committee on Drug Control ("ICDC"). This Charter was unanimously endorsed by the ICDC at our February meeting, and I therefore forward it to your attention with the Committee's recommendation for your ratification.

The Charter, as drafted, continues past practice in designating the ICDC as primarily a discussion and coordination forum. The major change in the Charter is that each agency's delegation will now report directly to a surrogate appointed by each respective agency head. It is my understanding that this will be Dr. Crout for FDA, Mr. Lawrence for NIDA, and Mr. Haislip for DEA. I view this change as a very positive one which will make the ICDC more accountable for its actions as well as ensure coordination between the staff and policy-making levels of each agency regarding matters brought before the Committee.

I would ask that you reach your decision on the Charter, if at all possible, before our next ICDC meeting which is scheduled for Thursday, March 5, 1981. If you have any questions, please call me at extension x34033 (outside line 443-4033). I look forward to working closely with you and members of the three agencies on drug control matters of mutual concern.

Joseph A. Levitt
Joseph A. Levitt

cc: Dr. Crout
Mr. Lawrence
Mr. Haislip

Charter should be approved

concur

non concur

Mark Haislip

MAR 13 1981

1-12-8

CHARTER

Interagency Committee on Drug Control (ICDC)

History

The Special Action Office for Drug Abuse Prevention (SAODAP) was created in 1972 to focus the resources of the Federal Government to significantly reduce the incidence of drug abuse in the United States within the shortest possible time period, and to develop a comprehensive, coordinated long-term Federal strategy to combat drug abuse. Under SAODAP direction, a committee was formed to coordinate efforts among those agencies involved in drug scheduling and control.

The Interagency Committee on Drug Control (ICDC) was formed and first met on November 15, 1973, to provide an informal forum for discussing important problem areas in drug control, under the CSA of 1970 and international conventions, that transcended the responsibilities of the individual agencies: the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA). In addition, the ICDC was needed to support the efforts of the heads of the member agencies in formulating broad policies for drug control and resolving major questions in the coordination of scheduling recommendations. In this way, it was intended that the entire drug control community would be kept abreast

of the activities of each agency's staff and advisory committees, and activities of each unit could be properly coordinated.

During its first two years, the ICDC was active in efforts to evaluate the impact of drug control regulations on drug abuse; to study the use of identifying logos on scheduled drugs; to initiate approaches toward encouraging good prescribing practices; to develop methodologies for measuring the abuse potential of drugs; to establish reasonable procedures for setting production quotas for drugs; and numerous other functions. The general working procedure for the Committee was for it to serve as a forum for coordination of each agency's response to the various issues arising in the drug control area. Members of the Committee were responsible for mobilizing the appropriate groups within each respective agency to carry out whatever work was necessary.

On June 30, 1975, the statutory authority of SAODAP expired. The NIDA Director recommended to the DEA Administrator and FDA Commissioner that although the ICDC was created to function under SAODAP direction, there was a need for an interagency forum of this type. It was additionally recommended that the chairmanship be rotated among the three agencies. Therefore, the ICDC has remained in existence functioning as a forum for discussion of drug control issues and problems, represented by the Drug Enforcement Administration, Food and Drug Administration, National Institute on

Drug Abuse and the White House Drug Abuse Policy Staff. For the remainder of 1975, each agency took turns serving as secret and chairperson. From 1976 to the summer of 1978, the ICDC was chaired by NIDA. From January 1980, the Drug Enforcement Administration chaired the ICDC.

Purpose

The Interagency Committee on Drug Control will serve as an informal forum for discussion of problem areas in drug control that transcend the boundaries of individual agency responsibilities, will help the entire drug control community to keep abreast of the activities of each agency's staffs and advisory committees, and will support the efforts of the heads of member agencies in matters relating to drug control.

The ICDC is not intended to be a substitute for specific agency responsibilities. It is not intended to alter existing statutory obligations or processes, but to facilitate the exchange and coordination of information when feasible.

Operation of ICDC

The ICDC will meet regularly and will include representation from DEA, FDA and NIDA. The chairmanship will be rotated every January among the three agencies, i.e., in 1980 by DEA, in 1981 by FDA, and in 1982 by NIDA, etc. The chairmanship and agency representatives shall be named by the Agency Head. It will be the responsibility of the presiding agency to replace a chairman if the designated chairman resigns or

retires during that agency's operating year for chairing the ICDC. It will also be the responsibility of each agency to replace its retiring or resigning representatives. At the end of the year, when the new agency takes over, the old chairman will be acting chairman until the new chairman is selected.

Three agency representatives will be named by each agency head; three alternate representatives shall be named. Meetings may also be attended by additional staff persons from the respective agencies, who may participate in the discussions. In the case of votes, only the 3 official representatives from each agency (or his or her alternate in the event an official representative is absent) may vote.

The meeting agenda will be provided and minutes kept. Agenda topics will be provided by the agencies represented. Non-government representatives will not be allowed to attend meetings, unless specifically permitted by a majority vote of the ICDC.

Function

The Committee through its individual members will report to the heads of member agencies or their delegated policy surrogates and advise them of significant developments affecting the coordination of drug control activities within the Federal Government. The Committee will in particular examine the following areas:

1. The domestic drug control process, including ways to improve interagency liaison and coordination in order to expedite control decisions.

2. Changes in the law and/or administrative procedures regarding the expeditious control of a drug when the abuse situation is critical.
3. Guidelines for control. Control is understood to mean decontrol or less restrictive control as well as tighter control.
4. The current schedules and criteria for scheduling drugs.
5. Consequences of various control decisions from the economic and legal, as well as the medical and enforcement, points of view.
6. International scheduling recommendations and resulting obligations with respect to drug control.
7. Other tasks and research studies as may properly and by mutual agreement be accepted by the Committee.

The Committee may make recommendations as to measures, including changes in organization, procedure and policy, to improve the coordination of drug control actions..