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Violations of the Hexachlorophene Ban in Monroe County, New York  
- Failure of FDA Regulatory Procedures*

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THE ROCHESTER COMMITTEE FOR SCIENTIFIC INFORMATION  
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Bulletin #152  
Product Safety

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Violations of the Hexachlorophene Ban  
in Monroe County, New York -  
Failure of FDA Regulatory Procedures  
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Summary

Products containing hexachlorophene in amounts greater than permitted by the Food and Drug Administration have been found on store shelves in Monroe County, N.Y. in December, 1972 in violation of an FDA ban on over-the-counter sales effective two months earlier. The FDA has just released a list of products containing hexachlorophene. Our survey found forty-five products which were not on the FDA list. This oversight by the FDA is difficult to explain since most of these products had appeared on an earlier, preliminary FDA list. The R.C.S.I. is aiding the retail merchants included in our survey to comply with the current controls on hexachlorophene.

Background

As of September 27, 1972, no product containing more than .75% by weight hexachlorophene may be sold without a prescription (1). Additional restrictions cover the production of any product to be made with hexachlorophene. The reasons for this ban and the other aspects of the FDA restrictions have already been discussed in another R.C.S.I. bulletin (2).

Since all products are not required to list their hexachlorophene contents (3), a simple shelf inspection is not sufficient to discover which products were banned and must be removed. Retailers, therefore, must rely on notification by their suppliers as to items to be removed from over the counter sale. Suitably reformulated versions of these products may be sold without restrictions. FDA rules now allow less than .1% hexachlorophene in most newly manufactured products except for products to be used on or near mucous membranes, for which no hexachlorophene is permitted. As has been previously noted (2), it will not be easy for the customer to distinguish some of the old formulae from the new ones.

The Food and Drug Administration compiled lists of all products covered by the Food, Drug and Cosmetic Act which had contained any amount of hexachlorophene including quantity as a percent of the total contents. A preliminary list of some hexachlorophene containing products was dated October 2, 1972 (7). Because the percentages were not given for all the products, this list was too inaccurate for use in enforcing the ban. Since information on the contents of every product is not normally supplied by manufacturers to the FDA, each FDA field office was directed to survey all potential manufacturers in its area and report back by October 27, 1972 the name, manufacturer, and the hexachlorophene content of every product which had contained hexachlorophene (4). As the FDA has jurisdiction only over products that must be manufactured in accord with the U. S. Food, Drug and Cosmetic Act, other products such as air filters or shoelaces which have been treated with hexachlorophene would not be included in the FDA list.

\* The author is working for R.C.S.I. under a Xerox Social Services Leave.

The FDA released its new, comprehensive list (5) of products that contained hexachlorophene in early December, 1972. Dated November 21, 1972, the list ran sixty pages and had over 1500 entries.

### Method

Using the comprehensive FDA list, the author prepared a list of items reported to contain more than .75% hexachlorophene. This list had over 300 entries. On December 4, 5, and 6 the shelves of seven large drug or discount stores were inspected for products containing hexachlorophene. Since the products could have been reformulated after they were put on the list, a product was considered to be in violation of the FDA regulations only if the label indicated that it contained hexachlorophene and if information that the amount of hexachlorophene was greater than .75% on the label, or on the FDA list, or both. If the amount of hexachlorophene on the label was below the amount on the FDA list, the label was accepted as the more accurate and up-to-date. A spot check of the products on the shelves was also made to check if all products which contained hexachlorophene (regardless of quantity) appeared on the FDA comprehensive list.

### Results

Every one of the seven stores had at least one product available that contained more than .75% hexachlorophene and should not have been accessible for over the counter purchase. These products should have been removed shortly after September 27, 1972. The stores and the products found in them are listed in Table 1.

During the inspection forty-five products containing hexachlorophene were discovered that were not listed by the FDA. These products are listed in Table 2. Most of these products did not include the amount of hexachlorophene on the label.

### Discussion

Most of the stores were notified on the spot of the products found to contain more than .75% hexachlorophene. These items were removed by the stores' personnel. All the stores were notified by mail. Talking to the store personnel revealed a number of reasons why the offending products were still on the shelf. Most often, the people said that they had never been notified to remove the product. In one instance the product was thought to have been returned to the store's wholesaler and then shipped back to the store as part of the stock of the reformulated product.

The forty-five items found that did not appear on the FDA list included some of the most advertised products made with hexachlorophene. Dial with AT-7 (hexachlorophene) made by Armour is one of these products not on the comprehensive FDA list. Other sources (6) suggest that some of these products contain more than .75% hexachlorophene. If this is so, sale of these items would be in violation of the current Food and Drug Administration's regulations.

The official FDA list had overlooked some of the major manufacturers (Johnson & Johnson, Mennen) whose products contained hexachlorophene, as well as some major divisions of other large companies (Lehn & Fink Division of Sterling Drug, both the Leeming and Pacquin Divisions of Pfizer). Many of the products of these companies had been listed on the preliminary list. For instance, although Dial soap and other Armour products were on the preliminary list, no Armour products appeared on the final, comprehensive FDA list. A copy of the corrections made by the R.C.S.I. has been forwarded to the FDA.

## Conclusions

Products that were in violation of the current FDA regulations on hexachlorophene were found on local store shelves, two months after the recall date. Also found were products containing hexachlorophene which were missing from the official FDA list of such products. The products that were missing from the list were not ones that were hard to find. Quite to the contrary, some of them had been widely used and some had been included on the first draft of the FDA list. It appears that the agency responsible for the safety of foods, drugs and cosmetics was not able to get a complete listing of products containing a banned ingredient or to get these products to be promptly removed from retail sales.

## References

- (1) Federal Register, Vol. 37 #188, Wednesday, September 27, 1972 p 20160
- (2) R.C.S.I. bulletin #148
- (3) Food, Drug and Cosmetic Act, title 21, United States Code
- (4) private communication, Mr. Ed Nida, FDA Press Office, Rockville, Md.
- (5) "A List of Hexachlorophene Containing Products" compiled by the Case Evaluation Branch, Division of Regulatory Operations, Office of Compliance, FDA, Rockville, Md., November 21, 1972
- (6) Wall Street Journal, September 25, 1972
- (7) "HCP Compliance List, October 2, 1972", FDA Press Office, Rockville, Md.

Table 1. List of Stores surveyed by the R.C.S.I., and of products that were offered for sale without prescription formulated with more than .75% hexachlorophene.

<u>Date &amp; Store</u>	<u>Manufacturer</u>	<u>Product</u>	<u>Hexachlorophene % content based on FDA list</u>
12-4-72	Key Drug, Webster Plaza		
	Westwood Pharm.	Fostex Cream	1.0(as per label)
	Alberto Culver	Subdue Shampoo	unk. above .75
	Gillette Toiletries	Regular Gillette Lather Shave Cream	1.02
	Cooper Labs.,Mystic,Conn.	Acnoveen Bar for Acne - Soap free	2.0(as per label)
	Cooper Labs.,Wayne N.J.	Acnoveen Bar	2.0(as per label)
12-4-72	Big N, Webster Plaza		
	Colgate Palmolive	Hyperphase	3.0
	Shulton	Ice-O-Derm Bar	.91
	Vick Chemical	Clearsil Medicated Soap	1.5
12-5-72	Clinton Drug, Webster		
	Alberto-Culver	Subdue Shampoo	unk. above .75
	Mitchum-Thayer	Facial Esoterica Skin Toner	2.0
	Mitchum-Thayer	Original Esoterica "	" 2.0
	Shulton	Ice-O-Derm Bar	.91

Table 1, continued

12-5-72 Freeman's Drug, Penfield

Norwich	Amolin Cream	1.0
Stiefel	Brasivol Rough Scrub	
	Cleanser for Acne	1.0
Stiefel	Brasivol Base	1.0
Mitchum-Thayer	Original Esoterica Med.	
	Skin Toner	2.0

12-5-72 Key Drug, Panorama Plaza

Mitchum-Thayer	Original Esoterica Med.	
	Skin Toner	2.0
Mitchum-Thayer	Facial Esoterica Med.	
	Skin Toner	2.0
Westwood Pharm.	Fostex Cream	1.0(as per label)

12-6-72 Topps, Henrietta

Pharm. Div.	Desenex Soap	2.0
Westwood Pharm.	Fostex Cream	1.0(as per label)
Shulton	Ice-O-Derm Bar	.91
Mitchum-Thayer	Original Esoterica Med.	
	Skin Toner	2.0

12-6-72 Rite-Aid, 1100 Jefferson Road, Henrietta

Mitchum-Thayer	Facial Esoterica Med.	
	Skin Toner	2.0
Mitchum-Thayer	Original Esoterica Med.	
	Skin Toner	2.0
Block Drug-Sterling	Tegrin Medicated Soap	1.0

Table 2. Products which indicate hexachlorophene as an ingredient but which do not appear on the FDA list of Nov. 21, 1972; found on the store shelves.

<u>Manufacturer</u>	<u>Product</u>
Lehen & Fink div.	Stridex Medicated Pads
Sterling Drug	Medi-Quik First Aid Spray
	Medi-Quik Sunburn Cooler
Bonne Bell	Ten-O-Six Treatment Shampoo
	Ten-O-Six Lotion
	Ten-O-Six Cool Gel
Westwood Pharm.	Fostex (1% as per label)
Alberto-Culver	Derma Fresh Medicated Hand Lotion
	Derma Fresh Hand Conditioner
	Derma Fresh Skin and Body Lotion

Table 2, continued

Helene Curtis	Enden Dandruff Shampoo (tube) Enden Dandruff Shampoo Liquid Enden Dandruff Shampoo Creme Enden Dandruff Shampoo for Dry Hair
McKesson	Soothe Skin Hospital Lotion Cut 'N Scratch Spray
Mennen	Medicated Face Cleaner Baby Magic Lotion
Mitchum-Thayer	Mazon Medicated Shampoo (.5% as per label)
Cooper Labs.,Mystic Conn.	Acnoveen Bar for Acne - Soap Free (2% as per label)
Cooper Labs.,Wayne, N.J.	Acnoveen Bar (2% as per label)
Purex (Compana Div.)	Cuticura Acne Cream Cuticura Talcum Spray
Plough	Solarcaine Lotion Solarcaine First Aid Spray Solarcaine Spray Solarcaine Foam Mexsana Medicated Powder Sulfur-8 (.15% as per label)
Johnson & Johnson	First Aid Cream Medicated Powder Baby Lotion with Hexachlorophene
Personal Products	Vespere Feminine Hygiene Mist Vespere Feminine Hygiene Spray Powder
Armour	Dial with AT-7
Leeming div. Pfizer	Unburn Cream Unburn Bottle Antibacterial Desitin Baby Powder Medicated Desitin Baby Oil
Pacquin div. Pfizer	Pacquin Medicated Hand Cream
S.E.Massengill	Massengill Feminine Hygiene Spray
Revlon-Pharmacel	Medicated Silicare Protective Lotion - Hands and Body
Andrew Jergens	Jergens Clear Complexion Gel for Acne
Sigma Pharm.	The Original Physicians' and Surgeons' Oily Skin Soap