

- (j) Adequate samples of incoming raw materials are taken and appropriate analysis of these samples made.
- (k) Preparation of manufacturing records and forms is done with such clarity, care and completeness as to eliminate mistakes and confusion.
- (l) Operations involving the weighing out of raw materials and the preparation of formulae and application of labeling are checked by another qualified party in addition to the employee originally performing such duties.
- (m) Returned goods are recorded, handled, stored, and again disposed of in a manner which will eliminate uncertainty, confusion, and the possibility of mistakes.
- (n) A representative of the U.S. Food and Drug Administration inspects the plant and determines that an adequate control system has been installed embodying all of the herein listed safeguards considered necessary to good pharmaceutical manufacturing practice.

6547. Menestrex capsules. (F.D.C. No. 43564. S. No. 56-778 P.)

QUANTITY: 660 12-capsule btls. and 108 25-capsule btls. at Atlanta, Ga.

SHIPPED: 6-8-59 and 7-13-59, from Nashville, Tenn., by Rex Laboratory.

LABEL IN PART: "Menestrex * * * Contains: Potassium Permanganate Quinine Sulphate."

LIBELED: 9-25-59, N. Dist. Ga.; amended libel filed 2-2-61.

CHARGE: 502(a)—when shipped, the bottle label bore false and misleading representations that the article was an adequate and effective treatment for easing distress in scanty or functionally difficult menstruation; 502(f) (1)—while held for sale, the labeling failed to bear adequate directions for use and the article was not exempt from that requirement; 503(b) (4)—while held for sale, the article was subject to 503(b) (1) (B) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Rex Laboratory, claimant, filed an answer denying that the article was misbranded as alleged and moved for a transfer of the case to another district. On 12-16-59, the court issued the following order:

HOOPER, *District Judge*: "Claimant has moved to transfer the trial of this action to 'a proper district of reasonable proximity to his principal place of business,' his business being located in Nashville, Tennessee, in the Middle District of Tennessee.

"He suggests removal to the Winchester Division of the Eastern District of Tennessee.

"His motion is based upon provisions of 21 U.S.C.A. § 334(a), which makes it mandatory upon the Court in a case of this nature to transfer the case, but there is an exception made in cases 'when such misbranding has been the basis of a prior judgment in favor of the United States in a . . . libel for condemnation proceedings under this chapter.'

"The Government resists the removal upon the sole ground that allegedly there have been 'prior judgments in this district condemning the exact same product.' Attached to the Government response are copies of three libels filed in this district concerning the same shipper and the same product and in two of the libels there is involved the same alleged misbranding, to-wit, that the libels 'are false and misleading since the article is not effective' in the treatment of the ailments involved.

"However, one of these libels was filed October 20, 1948, and it does not appear whether a judgment was taken or whether the proceeding was even opposed. The other libel was filed October 28, 1948, nothing appearing but copy of the libel petition.

"No cases are cited to this Court containing the language in 21 U.S.C.A. § 334(a) as to 'such misbranding.' However, this Court does not believe that a misbranding made the subject matter of libel proceedings in 1948 can be considered as the same misbranding involved in a libel filed September 25, 1959. As the record now stands the case would have to be removed.

"Removal of the case will be delayed, however, for a period of twenty days, during which the Government may make known to this Court whether or not there is any ground for retaining the case in this Court and constituting 'just cause' under the aforesaid statute.

"If the case is removed it is not the intent of the law that the defendant should be able to select the particular court to which it should be removed, that being left to the discretion of this Court. It would be the purpose of this Court to remove the case to the United States District Court adjoining the one in which defendant's place of business is located which has at the present time the smallest number of cases pending, and therefore defense counsel is directed to ascertain (from official reports of the Administrative Office, or otherwise) which district that would be."

The above order was vacated on 1-22-60, by the following order:

HOOPER, *District Judge*: "Order of Court of December 16, 1959 is hereby vacated and set aside after further study of this question and briefs submitted by all parties.

"The single question confronting the Court is whether or not claimant of the allegedly adulterated goods has a right under 21 U.S.C.A., § 334(a) to transfer this action from the Northern District of Georgia (the only District in which the goods in question were seized) to 'a district of reasonable proximity to the claimant's principal place of business' as provided in said statute.

"The Government, contesting the motion to transfer, has now cited for the first time the case of *Fettig Canning Company vs. Steckler*, 188 F. 2d, 715 in which this matter is thoroughly discussed. While the case just cited was a motion to transfer trial of a case such as this pursuant to 28 U.S.C.A., § 1404 (a), a full and complete discussion was also had concerning 21 U.S.C.A., § 334(a) herein involved.

"The point which was made clear, however, in the *Fettig* case, *supra*, is this:

"The Condemnation proceedings in question constitute an action in rem and the jurisdiction of the Court is limited to the district in which the goods were actually seized. As the goods in the cited case had moved from Indiana to Missouri and were seized in the latter state, the Court held that proceedings could not be transferred from Missouri to Indiana as attempted, for the reason that Indiana was not the jurisdiction where 'the action might have been brought' originally (see p. 717). The Court said that were it assured that the goods were subject to seizure in the Southern District of Indiana it would make no difference.

"While the foregoing applies to the general statute as to transfers, the Court further stated:

But when we come to § 334, the one here involved, the proceeding is directed at an article and not a person, and while the person who claims to be the owner or interested in the libeled goods is permitted to come in as a claimant, it is not necessary that such person be a party to the proceeding. All that is required is that the libeled articles be found in the District, and this limitation upon jurisdiction appears to have been imposed deliberately and not as a result of any inadvertence.

"In the cited case it is also pointed out that 'Congress has made no provisions by which such a decree could be made effective beyond the territory of the district wherein the case was tried.'

"While § 334(a) does contain a proviso that no libel for condemnation shall be instituted for misbranding 'if there is pending in any court a libel for condemnation proceedings . . . based upon the same misbranding,' and also provides that 'not more than one such proceeding shall be instituted if no such proceeding is pending,' there is an exception to the effect that such limitations shall not apply 'when such misbranding has been the basis of a prior judgment in favor of the United States in a libel for condemnation proceedings

under this chapter.' While a great deal of discussion has been had by counsel for both sides on the question of venue, it seems to this Court that it pertains not to venue so much as to multiplicity. It makes it clear, however, that the fact, as shown by this record, that there have been several prior judgments against the same claimant growing out of the same misbranding of the same articles, that is no obstacle to the present proceedings. The language relied upon by defendant commanding a transfer of the case, must be taken however in the light of the limitation that it applies 'in any case where the number of libels for condemnation proceedings is limited as above provided.' The language would seem to indicate that if there were more than one seizure it would be the duty of the trial judge to transfer the action from a jurisdiction remote from the claimant's residence to one in reasonable proximity to the same. However, no ruling to this effect is made as the Court could be in error as to the meaning of the language.

"The Court's refusal to granting the change of venue is therefore placed upon the ground that this is an action in rem and the jurisdiction of this Court is based upon the fact that the seizure was had in this district and this Court cannot transfer the case to another district where no seizure was had, even though a seizure in such other district could have been had.

"Motion for change of venue is denied."

The Government subsequently filed written interrogatories which were answered by the claimant on 6-6-60. Thereafter, the libel was amended to include the charges of misbranding under 502(f) (1) and 503(b) (4) as set forth above, and, on 3-7-61, a motion for summary judgment was filed by the Government on the basis that there were no genuine issues of material fact precluding judgment for the Government. On 3-22-61, the court granted the Government's motion for summary judgment and ordered the article condemned and destroyed.

6548. Peyote and peyote extract capsules. (F.D.C. No. 44571. S. Nos. 33-880 R, 34-806/7 R.)

QUANTITY: 6 ctns. containing a total of 294 lbs. and reused paper bags containing a total of 20 lbs. of *peyote*; and 29 unmarked envelopes containing 5 capsules each of peyote extract, at New York, N.Y.

SHIPPED: On 4-22-60, the 294-lb. lot and on 12-17-59, the 20-lb. lot, from Laredo, Tex., by Smith's Cacti Ranch.

LABEL IN PART: (Ctn.) "From: Smith's Cacti Ranch, P.O. 736, Laredo, Texas To: Barron Bruchlos, 234 Mulberry Street, New York, New York * * *"; (bag) "French Roast Flavor Cup Coffee * * * 1 Lb. Net."

RESULTS OF INVESTIGATION: Examination of the article in the 294-lb. and 20-lb. lots showed it to be *peyote*. The article in the capsules contained alkaloids of peyote and had been prepared from some of the *peyote* in the 20-lb. lot under the direction of the consignee of the articles, Barron Bruchlos, t/a Cart Wheel Coffee Shop.

LIBELED: 5-17-60, S. Dist. N.Y.

CHARGE: 502(b)—when shipped and while held for sale, the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of the contents; 502(d)—the articles were a hypnotic substance, namely, *peyote*, and their labels failed to bear the name, quantity, or proportion of such substance and, in juxtaposition therewith, the statement "Warning—May be habit forming"; 502(e) (1)—the labels of the articles failed to bear the common or usual name of the articles; 502(f) (1)—the labeling of the articles failed to bear adequate directions for use; 503(b) (4)—the articles were drugs