

[54] LABEL USEFUL FOR BLIND CLINICAL STUDIES OF A MEDICAMENT AND METHOD OF THE MANUFACTURE THEREOF

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[51] Int. Cl. .... B42d 15/00, G09f 3/00, B32b 13/00

[58] Field of Search ..... 283/6, 21; 161/406, 161/410, 413, 268; 40/310, 312, 2 R

[56] References Cited

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3,593,443	7/1971	Demetrius.....	40/2 R
3,594,928	7/1971	Noel .....	283/6 X
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Attorney—Robert L. Niblack

[57] ABSTRACT

A label useful for blind clinical studies of the effects of a particular medicament comprising a water-soluble paper having only revealable information printed thereon, integrally bonded to and coextensive with a water-insoluble paper having both revealable and secret information printed thereon. Only the revealable information is visible on the label until the label is washed in water.

12 Claims, 4 Drawing Figures

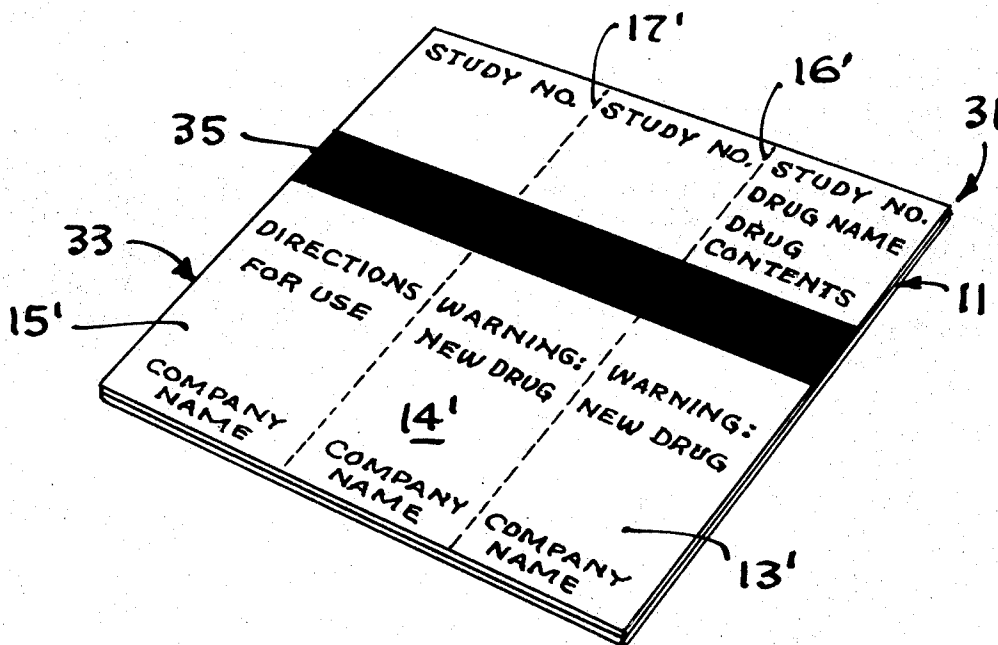


FIG. 1

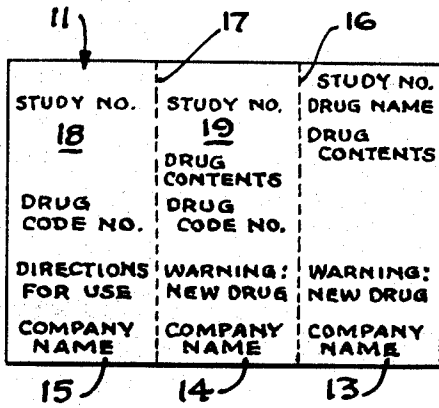


FIG. 2

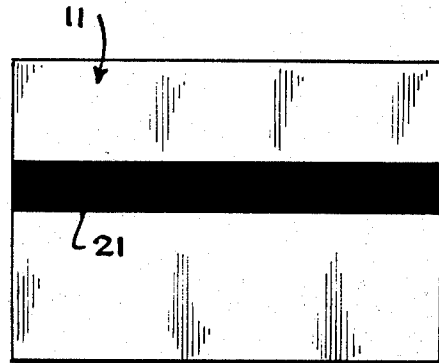


FIG. 3

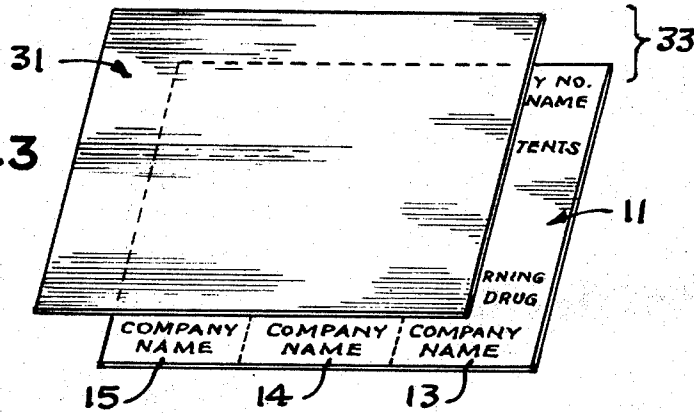
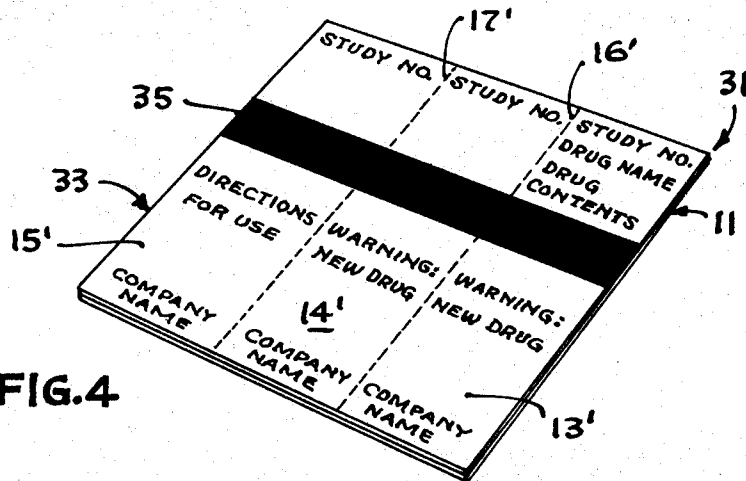


FIG. 4



# LABEL USEFUL FOR BLIND CLINICAL STUDIES OF A MEDICAMENT AND METHOD OF THE MANUFACTURE THEREOF

## BACKGROUND OF THE INVENTION

This invention relates to labels and, more particularly, to labels useful for blind clinical studies of the effects of a particular medicament, such as the label disclosed by U.S. Pat. No. 3,593,443 granted to Julius C. Demetrius, Jr. and assigned to Merck and Co., Inc.

To obviate psychological or subconscious effects stemming from the physician or the patient, it is not desirable in clinical studies to reveal to either the physician or the patient whether or not the medicament being administered to that patient contains the medicament whose effects are being clinically tested, or is merely a placebo having the appearance of that medicament. Or, if the contents of the medicament are so revealed, the amount contained therein is not revealed. Such nondisclosure is necessary for the maintenance of a valid, blind or double-blind, clinical study of the medicament.

Conflicting with the need for not revealing the true contents of a particular medicament to the physician or patient is the occasional medical need for either the physician or patient to promptly learn the true contents of the medicament. Such a need can arise from a large number of situations involving the patient's health, e.g., an unexpected reaction apparently resulting from taking the particular medicament administered or an automobile accident.

Accordingly, it is desirable that the means used for presenting revealable information to the physician and patient also provide means for promptly presenting nonrevealable or secret information to the physician or patient when it is actually needed. Additionally, the means used to present the secret information to the physician or patient should only reveal that information necessary for the needs of the particular patient in need, to obviate the possibility of revealing secret information about the medicament for any other patient involved in the same blind clinical study.

Further, the means so used should be substantially tamper-proof and should readily indicate when it has been tampered with and finally, should be easily and inexpensively manufactured and used.

## SUMMARY OF THE INVENTION

Therefore, the primary object of the present invention is to provide a label for a medicament being clinically studied which will satisfy the aforementioned requirements and preferences.

More particularly, it is an object of the present invention to provide a label for a medicament that presents only revealable information to the physician and patient, yet provides means for easily and promptly ascertaining secret information about a medicament when it is needed.

Other objects are to provide such a label that is easily and inexpensively manufactured and used, substantially tamper-proof, readily indicates when it has been tampered with and only reveals secret information for the particular patient in need thereof when its secret compartment is interrogated.

In accordance with these and other objects, there is provided by the present invention a label that only reveals disclosable information to a physician or patient

until the label is washed in water, whereupon both the revealed and additional secret information is provided by the label. The label comprises a substantially water-insoluble paper having information consisting of predetermined revealable and secret portions printed on a first side thereof and a water-soluble paper integrally bonded to and coextensive with the insoluble paper. The soluble paper has only the revealable portion of the above-described information printed thereon and exactly superimposed over the revealable information on the insoluble paper. Preferably, a solid dark band can be printed over and under the secret information on the soluble and insoluble papers respectively.

## BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and attendant advantages will become obvious to those skilled in the art by reading the following detailed description in connection with the accompanying drawings, wherein like reference characters designate like or corresponding parts throughout the several figures thereof and wherein:

FIG. 1 is a plane view of a first side of the water-insoluble paper of one embodiment of the label of the present invention;

FIG. 2 is a plane view of a second side of the paper shown in FIG. 1;

FIG. 3 is an exploded view of the water-soluble and insoluble papers of one embodiment of the label of the present invention; and

FIG. 4 is an isometric view of the papers shown in FIG. 3.

## DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, there is shown in FIGS. 1-4 a preferred embodiment illustrative of the label of the present invention. In FIG. 1, there is shown a substantially water-insoluble paper 11. For purposes of this specification, the term "paper" is defined to include any substance acceptable for printing thereon, regardless of its composition. Preferably, insoluble paper 11 can be 45 lb., English Finish Stock.

Paper 11 is divided into sections 13, 14 and 15 by dashed lines 16 and 17. Paper 11 has printed on a first side thereof information consisting of predetermined revealable and secret portions. Illustratively, study numbers, directions for use, warnings regarding use of the medicament and the manufacturing company's name can constitute the revealable information, while the code number and contents of the medicament can constitute the secret information. Preferably, the printing on paper 11 is done with water-insoluble ink.

In FIG. 1, the predetermined secret portions of the printed information are designated 18 and 19. While the secret portions 18 and 19 are physically located in juxtaposition, they may be physically separated from each other, if so desired. Further, as in FIG. 1, when paper 11 is divided into sections, each section of paper 11 may or may not have secret information printed thereon. Also, some information treated as secret on one section, may be treated as revealable on another section, depending on the ultimate recipient of each particular section.

Depending on the particular insoluble paper used, secret portions 18 and 19 may be visible from the opposite side of paper 11, especially if exposed to a bright light. Therefore, it is preferred to print a substantially solid band 21 with dark ink on a second side of paper

11 underlying secret portions 18 and 19 on the first side thereof, as shown in FIG. 2. Although band 21 is shown as a rectangle in FIG. 2, it may assume any shape necessary to make secret portions 18 and 19 invisible, and may or may not extend the entire length or width of paper 11.

As shown in FIG. 3, a water-soluble paper 31 is placed over the first side of insoluble paper 11. Soluble paper 31 is coextensive with and integrally bonded to insoluble paper 11 to form the composite label 33. Preferably, soluble paper 31 is a rice paper and a water-soluble, pressure sensitive adhesive is used to bond the two papers.

Soluble paper 31 has printed thereon only the revealable portion of the information printed on insoluble paper 11 and it is exactly superimposed thereover. Preferably, soluble paper 31 is bonded to insoluble paper 11 before the revealable information is printed thereon. However, soluble paper 31 can be printed before it is bonded to insoluble paper 11, if desired, and depending on the opacity of soluble paper 31, the printing can be on either side thereof. Papers 11 and 31 can be any color desired and need not be the same color.

Further, as shown in FIG. 4, it is preferred to print a substantially solid band 35 of dark ink on soluble paper 31 overlying the secret portions 18 and 19 printed on insoluble paper 11. Obviously, band 35 can assume any shape or dimension that is necessary to make secret portions 18 and 19 invisible on the face of label 33. If soluble paper 31 is sufficiently opaque, band 35 can be eliminated. As shown in FIG. 4, the composite label 33 is divided into readily separable sections 13', 14' and 15' by perforated lines 16' and 17'.

It is contemplated that section 15' of the preferred embodiment of the present invention shown in FIG. 4 will be adhesively affixed to a container for a particular medicament being clinically studied. Thus, section 15' will ultimately be in the possession of the patient receiving the medicament being studied. Further, it is contemplated that section 13' will be retained by the manufacturer of the medicament, while section 14' will be retained by the administering physician. Obviously, the relative positions of sections 13', 14' and 15' can be interchanged without detracting from the usefulness of the label.

Label 33, as shown in FIG. 4, reveals only that information to the recipient of each section thereof that is deemed appropriate by the clinician conducting the blind clinical studies of the particular medicament. Yet, if a situation arises wherein either the physician or patient involved needs to rapidly obtain the true contents of the particular medicament involved, that secret information can readily be obtained by the easy and inexpensive washing in water of the section of the label respectively in the possession of either of them. Advantageously, once the soluble paper 31 has been washed away, none of the previously revealed information is lost, because it is also printed on the insoluble label.

Still another advantage of the label of the present invention is that one cannot readily recognize that the label is a composite of two papers. Accordingly, if so desired, the physician and/or patient involved need not be made aware of the location of the secret information until it becomes necessary for them to know it, thereby lessening any temptation to tamper with the label. To that end, it has been found to be advantageous to print the information on the soluble paper 31 with a darker

shade ink than that used on the insoluble paper 11, thereby further rendering the information printed on insoluble paper 11 less visible.

Finally, attempts to tamper, or actual tampering, with the label 33 are readily detectable, because once the soluble paper 31 is exposed to water, it cannot be repaired. Further, it has been found that most water-soluble papers used for the label are sufficiently heat-sensitive that any substantial exposure to the heat of a bright light will cause discoloration of the label. Also, it has been found that by making soluble paper 31 one color and insoluble paper 11 another color, detection of any tampering with the label is enhanced. Still further, because papers 11 and 31 are coextensive and integrally bonded, they cannot be separated without such tampering being readily apparent.

Having now described the invention in specific detail and exemplified the manner in which it may be carried into practice, it will be readily apparent to those skilled in the art, that innumerable variations, applications, modifications and extensions of the basic principles involved, may be made without departing from its sphere or scope.

That which I claim is:

1. A label for use in blind clinical studies of a medicament comprising:

a substantially water-insoluble paper having information consisting of predetermined revealed and secret portions printed with substantially water-insoluble ink on a first side thereof, and

a water-soluble paper coextensive with and integrally bonded to said first side of said insoluble paper, said soluble paper having only said revealed portion of said information printed thereon and exactly superimposed over said revealed portion on said insoluble paper;

whereby only said revealed portion of said information is visible on said label, until said label has been washed in water.

2. The label described in claim 1 wherein said information printed on said soluble paper is a darker shade than said information printed on said insoluble paper.

3. The label described in claim 1 and further including a substantially solid band of dark ink printed on a second side of said insoluble paper and underlying said secret portion of said information on said first side thereof.

4. The label described in claim 3 and further including a substantially solid band of dark ink printed on said soluble paper and overlying said secret portion of said information printed on said first side of said insoluble paper.

5. The label described in claim 1 and further including a substantially solid band of dark ink printed on said soluble paper and overlying said secret portion of said information printed on said first side of said insoluble paper.

6. The label described in claim 1 wherein at least one perforated line divides said label into readily detachable sections.

7. A method of manufacturing a label for use in blind clinical studies of a medicament comprising:

printing with substantially water-insoluble ink information consisting of predetermined revealed and secret portions on a first side of a substantially water-insoluble paper,

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integrally bonding a coextensive water-soluble paper to said first side of said insoluble paper, and printing only said revealed portion of said information on said soluble paper in a manner such that said revealed information on said soluble paper is exactly superimposed over said revealed information on said insoluble paper;

whereby only said revealed portion of said information is visible on said label, until said label has been washed in water.

8. The method of claim 7 wherein said information printed on said soluble paper is a darker shade than said information printed on said insoluble paper.

9. The method of claim 7 and further including the step of printing a solid band of dark ink on a second side of said insoluble paper, which band on said insolu-

ble paper underlies said secret portion of said information on said first side thereof.

10. The method of claim 9 and further including the step of printing a solid band of dark ink on said soluble paper in a manner such that said band on said soluble paper overlies said secret portion of said information on said insoluble paper.

11. The method of claim 7 and further including the step of printing a solid band of dark ink on said soluble paper in a manner such that said band on said soluble paper overlies said secret portion of said information on said insoluble paper.

12. The method of claim 7 and further including the step of perforating said label to divide said label into at least two readily separable sections.

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