April 3, 1962 C. NICOLLE 3,028,002

PACKAGE OF PHARMACEUTICAL COMPOSITION AND THE LIKE MOLDED IN SITU

Filed June 30, 1958 2 Sheets-Sheet 1

Fig. 1

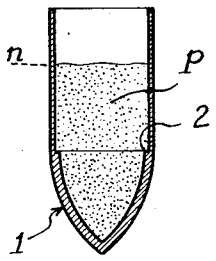


Fig. 2

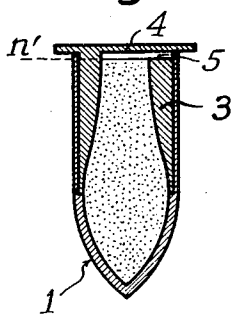


Fig. 3

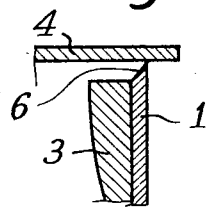


Fig. 4

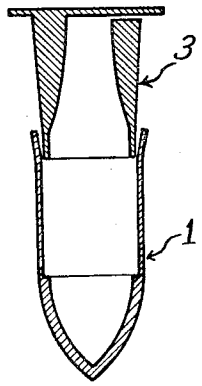


Fig. 5

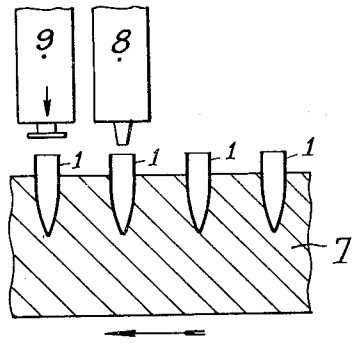


Fig. 6

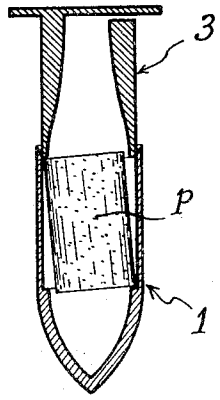
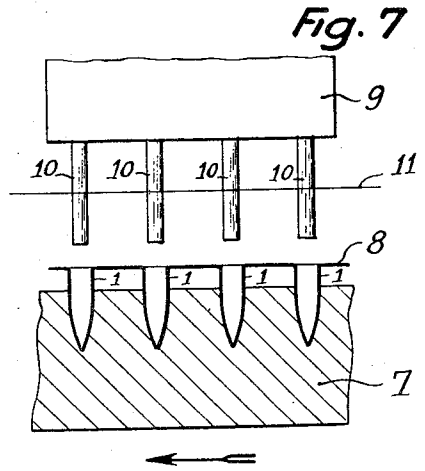


Fig. 7



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PACKAGE OF PHARMACEUTICAL COMPOSITION AND THE LIKE MOLDED IN SITU

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Fig. 8

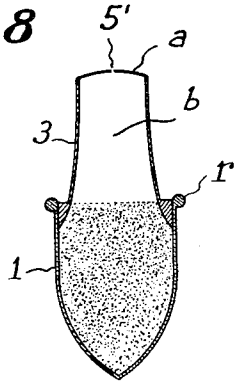


Fig. 9

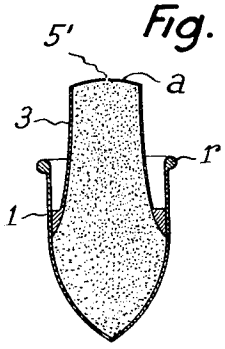


Fig. 10

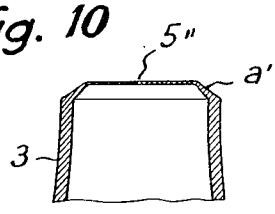


Fig. 11

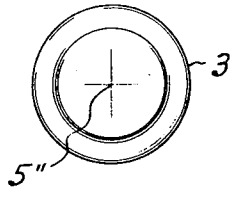
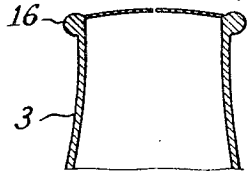


Fig. 13



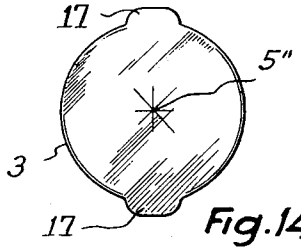


Fig. 14

Fig. 12

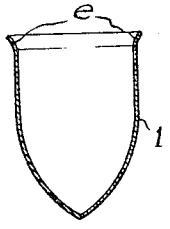
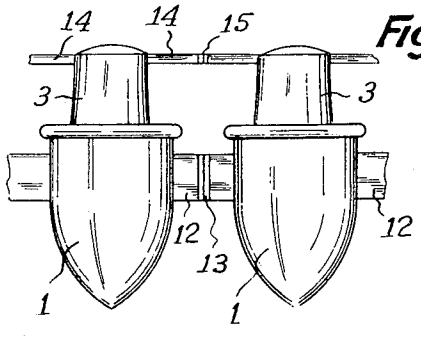


Fig. 15



United States Patent Office 3,028,002 Patented Apr. 3, 1962

3,028,002

PACKAGE OF PHARMACEUTICAL COMPOSITION AND THE LIKE MOLDED IN SITU

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Filed June 30, 1958, Ser. No. 745,751
Claims priority, application France July 1, 1957
2 Claims. (Cl. 206—63.2)

This invention relates to the production of packages of moldable compositions, especially pharmaceutical compositions, which are molded in situ i.e. within the packing means in which they are dispensed. The invention more especially relates to the production of suppositories, though it is by no means restricted thereto.

It is already known to mold suppositories and the like directly within the packing means in which they are eventually delivered to the market, by pouring metered amounts of the fluid or semi-fluid composition into receptacles having the desired inner configuration of the final suppositories, whereby such receptacles serve both as the molding and the packing means for the finished articles. However, such procedure as heretofore used has a number of drawbacks which it is a general object of the present invention to overcome.

Heretofore the means serving both as the molds and the packing means for such articles were sometimes provided in the form of a single unitary receptacle having a top opening through which the fluid composition was poured, and a flat strip sealing this opening. Such a form of packing means was satisfactory where the molded article or suppository had a simple ogee-like configuration, i.e. a cylindrical body tapered to a point at one end. However, where the molded article is to have a torpedo-like configuration, i.e. having an intermediate diameter larger than the diameter at either end, as is frequently required, a packing mold of the kind just referred to is unsuitable because the article cannot then be readily withdrawn out of the packing. In such cases, three-part packing molds have had to be used, including a two-part body section or main receptacle separable either in an axial or a transverse direction, and a flat end cover. This three-part construction has greatly complicated the manufacturing process. An object of the invention therefore, is to provide a form of combined molding-and-packing means for articles of the type described, which will be in two parts for simplified production and yet will allow of easily extracting the finished article from its packing even in cases where said article is of the torpedo-like shape specified above.

Other objects are to provide packages of composition molded in situ, which will be easier and more economical to produce in large quantities, will contain more accurately metered amounts of composition per package, will be more uniformly and perfectly sealed for prolonged storage life, and handier to use, as compared to similar products of the prior art. Objects of the invention also relate to methods of producing such improved packages.

In accordance with an important aspect of the invention, there is provided a package of molded composition comprising a pair of receptacles each sealed at one end and open at the other, one receptacle fitted into the other to define therewith a sealed mold cavity, and a body of said composition molded in situ within said cavity.

In accordance with another aspect, there is provided a method of preparing finished packages of molded composition comprising, relatively displacing a linear array of upwardly-open first receptacles successively past overhead metering and sealing stations, feeding a metered amount of said composition in fluid or semi-fluid state into each first receptacle as it is positioned under a metering station, inserting a downwardly-open second receptacle into each filled first receptacle as the latter is positioned under

a sealing station so that said composition fills the free spaces defined between said first and second receptacles, said second receptacles having top vents for discharge of air from said spaces, and allowing said metered amounts of composition to set within said spaces to provide the finished packages.

The above and further objects, features and advantages of the invention will appear from the ensuing description relating exemplary embodiments of the invention selected for illustrative purposes but not for limitation, with reference to the accompanying drawings, wherein:

FIGURE 1 is sectional view of the body member of a packing mold according to the invention containing the metered amount of composition filling the member to a predetermined height;

FIGURE 2 is a view similar to FIGURE 1, after insertion thereinto of a sleeve member according to the invention;

FIGURE 3 is a partial view showing a modification of FIGURE 2 on an enlarged scale;

FIGURE 4 is similar to FIGURE 2 but relates to another modification;

FIGURE 5 is a highly simplified view of apparatus for performing the molding and sealing process of the invention according to one form thereof;

FIGURE 6 is similar to FIGURE 2 but relates to another modification wherein the composition is introduced into the body member of the packing mold in the form of a cylindrical slug or paste-like consistency;

FIGURE 7 is a highly schematic view of apparatus for filling the body members of the packing molds in accordance with the method of FIGURE 6;

FIGURE 8 is an axial view of another form of packing mold according to the invention filled with a metered amount of composition, before the shaping sleeve has been pushed in;

FIGURE 9 is a view similar to FIGURE 6 showing the components in their final position after the product has been shaped;

FIGURE 10 is a sectional view of a modified construction of the upper or end portion of the shaping sleeve;

FIGURE 11 is an overhead plan view of the shaping sleeve shown in FIGURE 8;

FIGURE 12 is a sectional view of a modified construction of the body member of the packing mold;

FIGURE 13 is a sectional view of another form of the upper part of the shaping sleeve, being generally similar to FIGURE 8;

FIGURE 14 is a plan view of another modified form of the upper portion; and

FIGURE 15 shows part of a bunch of packing molds according to the invention.

In the illustrated embodiments of the invention to be described, particular reference will be made to the packing of suppositories, and more particularly still to the packing of suppositories of the "torpedo" type as earlier defined. It should be expressly understood however that the teachings of the invention are essentially applicable to packing means for suppositories of other shape, i.e. ovoidal, as well as to a wide range of other articles of moldable and shapable character.

As shown in FIGURES 1 and 2, the packing mold according to one form of the invention comprises two main components, a first receptacle or body member **1**, and a second receptacle or shaping and sealing sleeve member **3**. The body member **1** comprises a generally cylindrical part with an ogival bottom end. The inner surface of the body member **1** or first receptacle is formed with a shoulder **2** defined at the root of the ogival portion which is of greater thickness than the cylindrical portion, thereby providing the said shoulder. The shoulder **2** serves to seat the lower end of the sleeve member **3** as shown in

FIGURE 2. The sleeve member or second receptacle 3 has an outer diameter corresponding to the inner diameter of the cylindrical part of the first receptacle 1, so as to be a friction fit therein. When inserted home so that its lower end is seated against shoulder 2, the inner surface of the second receptacle or sleeve member 3 at its lower end seated against said shoulder, corresponds exactly to the inner diameter of the ogival end portion of the first receptacle. The inner diameter of the sleeve 3 then gradually decreases upwards from its said lower end, for example according to the contour shown, in order to define an inner free space corresponding exactly in contour to the outer contour of the molded article to be provided; herein this shape is that of a "torpedo" like suppository having a maximum diameter at the shoulder 2.

Formed solid with the upper end of the shaping sleeve 3 is a flat sealing wall 4, so that it will be seen that the shaping member and the sealing member herein constitute an integral unit. A side vent hole 5 is formed at the top of the sleeve to permit discharge of air entrapped between the upper surface of the contents and the sealing wall 4, when the sleeve 3 is forced into the body 1.

The packing mold described is used in the following way. The product *p* to be packed, preferably in liquid or semi-liquid form, is poured into the body member 1 up to a predetermined level *n* therein, as shown in FIGURE 1, such level being spaced a substantial distance from the uppermost end of the body 1. The shaping and sealing sleeve 3 is then inserted into the body, whereupon the air escapes through the vent 5 and the liquid level rises up to the level *n'*. At this time the packing operation is complete, and it is simply necessary to allow the filled packing mold to cool down so that its contents will set, without any special precautions.

As shown in FIGURE 3, the open upper end of the body part 1 may be formed with a bevel as at 6, or with an equivalent rounded flared or funnel-like shape to facilitate insertion of the sleeve 3.

A modified construction is shown in FIGURE 4 wherein the inner surface of the cylindrical part of the body 1 and the outer surface of the sleeve 3 are formed with a complementary tapered shape preferably over part of their vertical extent so that, on insertion of sleeve 3 into body 1, the tapered surface of the sleeve is a tight fit in the tapered surface of the body.

In FIGURE 5 one arrangement is schematically illustrated for filling the packing molds of the invention whereby the articles are simultaneously shaped and the packing molds sealed. As shown, a set of first receptacles 1 of the packing molds e.g. according to the form shown in FIGURE 1, are disposed in a movable frame 7 positioned under a metering feeder 8 of conventional type operable, when an empty first receptacle is positioned below it, for introducing a metered dose of fluid or semi-fluid substance into the first receptacle 1 up to the prescribed level *n* therein. The frame 7 is then shifted in the direction indicated by the arrow, to bring the filled first receptacle to a position underlying a device 9 serving to insert the second receptacles 3 into the first receptacles 1 over the contents thereof. At the same time, the leftward shifting of the frame 7 has brought the next following first receptacle 1 on the frame to a point underlying metering feeder 8 so that it can be filled simultaneously with the insertion of the second receptacle into the previously filled first receptacle by the device 9. This procedure can be repeated any desired number of times.

While the body members 1 of the individual packing molds have so far been described and illustrated as elements separate from one another, this is by no means essential and in fact the invention particularly contemplates that embodiment wherein all the first receptacles 1 are integrally interconnected. The interconnections may take the form of connecting flanges at the upper ends of the body members 1 or connecting strips extending between the adjacent body members in a common plane such that it contains the center axes of all the members. Similarly, the shaping and sealing sleeve members 3 may be connected to one another rather than being separate as shown e.g. in FIGURE 2. In this manner an integral bunch may be provided comprising any desired number of similar packing molds; and if desired frangible areas, such as lines of perforations or the like, may be provided between the adjacent packing molds to facilitate tearing them off one by one on demand.

It will be noted in connection with the filling process shown in FIGURE 5 that owing to the fact that the contents *p* filling the body members 1 only reaches up to a point short of the upper opening of said member, no trouble is experienced during the successive shifting steps of the frame 7 as described above, due to the possibility that would otherwise be present of the liquid contents of the body members splashing out as each newly filled body member is shifted from filling station 8 to sealing station 9. If the body members were filled completely as is usually the case in the prior art, such splashing would result in loss of substance and non uniform filling as well as soiling the outer surfaces of the packing and apparatus. However, if desired either for further preventing such splashing or for any other reason, the frame 7 with the mold members 1 thereon may be provided stationary, and the units 8 and 9 may be provided movable instead.

As already mentioned the sleeve member or second receptacle 3 serves the twofold function of a shaping member, in cooperation with the body member 1, and a sealing means. This is advantageous both in that it reduces the number of separate component elements of each packing mold to no more than two, and because it similarly reduces the number of separate operations involved in the molding and packing process, to a filling step and a sealing step. These are characteristic features of the invention and result in a greatly increased efficiency and economy of the molding and packing operations.

An additional advantage achieved through the arrangement described, is the excellent seal obtained, due to the integral character of the top flange 4 with the sleeve 3, in contrast with what is had with separate sealing strips as generally used with conventional packing molds of this kind, wherein the bonding of the strip is apt to be non-uniform and portions of the liquid contents are apt to be lodged between the mold and the sealing strip, especially due to the aforementioned splashing effect, thereby interfering with proper bonding of the strip.

FIGURE 6 illustrates yet another embodiment wherein the substance *p* rather than being poured in liquid form into the body member 1, is introduced in the form of a cylindrical slug of paste or pulp. The subsequent insertion of the shaping and sealing sleeve 3 into the body under suitable pressure, deforms the semi-solid slug and forces it to its final shape as determined by the body member 1 and sleeve member 3.

A suitable filling or packing arrangement for use with this form of the invention is shown in FIGURE 7. As shown, a frame 7 is arranged to carry a set of first receptacles 1 of the kind shown in FIGURE 1 or FIGURE 6, and it is here assumed by way of example that all these members are interconnected together by connecting flanges 8, though the members 1 could obviously be separate as shown in FIGURE 5. Overlying the frame is a feeding unit 9 which may comprise any suitable extruding means, and delivers a predetermined number of cylindrical sausage-like elements 10 respectively overlying a corresponding number of the members 1. Suitable means such as a wire 11 are provided for cutting off predetermined lengths of the elements 10 which then drop into the underlying members 1. The frame 7 is then shifted a suitable distance leftward as shown by the arrow so that the newly filled body members 1 are moved to a position underlying a sealing device (not shown)

for applying the sleeve members 3 as previously described. The insertion of the sleeves 3 is effected at suitable temperature depending on the nature of the contents to be packed so as to impart to the slug of material *p* the necessary plasticity.

It will be understood that, while FIGURE 5 shows a metering and feeding device 8 and a sealing device 9 each of which cooperates with only a single member 1 at a time, and while FIGURE 7 illustrates a feeding device 9 cooperating with a plurality of members 1 at a time and whereas the sealing device (not shown) referred to in connection with this figure was also said to cooperate with the same plurality of members simultaneously, such arrangements are by no means essential; thus in FIGURE 5 each of the devices 8 and 9 could be of a multiple or manifold character as the device 9 in FIGURE 7, while in FIGURE 7 the device 9 might be arranged to extrude only a single sliver of pasty material.

In the embodiment of the invention shown in FIGURES 8 and 9, the second receptacle or shaping sleeve 3 instead of being thick-walled as so far shown, is made from thin flexible sheet material, such as polyethylene or the like, so that its outer contour is reduced as well as its inner contour, rather than being generally cylindrical. This embodiment achieves an economy in packing material, and has another advantage in that it facilitates expulsion of the contents, e.g. suppository, by finger pressure out of the member 3.

The body member 1 is preferably made of a relatively hard plastic such as polystyrene or the like, which is inexpensive, though it should be understood that it may also if desired be made of flexible sheet material similar to the sleeve member 3. Another advantage of using a relatively hard plastic material for making the body member 1 is to facilitate the insertion of the sleeve 3 into it without tending to deform the body member 1. In fact the combination of a relatively stiff body member 1 (e.g. of polystyrene) with a relatively flexible sleeve member 3 (e.g. of polyethylene) provides an especially desirable combination in that it permits of inserting the sleeve members with the exertion of only very slight pressure. The requisite seal may be assured by imparting to the sleeve 3 at its lower end an outer diameter slightly larger than the maximum inner diameter of the body member. As already described with reference to another embodiment, insertion of the lower end of sleeve 3 into body 1 may be further facilitated by imparting to the upper end of the body 1 a slightly outwardly flared shape, as shown at *e* in FIGURE 12, or rounded as shown in FIGURES 8 and 9. These latter figures also illustrate an annular bead *r* surrounding the upper end of body member 1 which serves to impart increased rigidity to the body member as well as facilitating the filling and sealing operations. It will be understood that various other modifications of shape may be applied to the upper end of the body member 1.

Preferably, as shown in FIGURES 8 and 9, the sealed upper end wall *a* of the sleeve member 3 is slightly domed, and is very thin so as to yield readily and deform upwards under light finger pressure. This facilitates expulsion of the suppository in case it tends to stick to the walls of the sleeve 3.

Alternatively to the domed shape just described the upper wall *a* may be trapezoidal in cross section, i.e. in the shape of a cone frustum, as shown at *a'* in FIGURE 10. Both the vertical depth dimension of the domed wall *a* and that of the frustoconical wall *a'* may be quite small, and in fact said wall can suitably be made flat in those cases where the wall is made from highly flexible sheet material of sufficiently high resiliency, such as polyethylene, and sufficiently low thickness, and even concave, since pressure exerted on the sides of the sleeve will then deform said end wall to expel the suppository or the like from the sleeve.

To permit discharge of the air entrapped at *b* (FIGURE 8) on insertion of the sleeve 3, a minute hole 5' may be provided in the end wall *a*, small enough so that the air will only be able to pass through it under the effect of pressure, specifically the air pressure developed in *b* on insertion of the sleeve 3 into the body. After the air has been discharged from *b* and both components 1 and 3 are properly positioned with respect to each other, the orifice 5' is in effect sealed, and as impenetrable to outside air. Even should the suppository or other contents of the packing mold happen to melt at any time, it will not be able to flow out through the orifice 5' in view of its extremely small area.

Instead of the pinprick orifice 5' the aforementioned vent may be provided in the form of one or more slot-like incisions 5''. There may be a single cut, as in FIGURE 10, or there may be two crossed cuts as in FIGURE 11 or a greater number forming a star pattern as in FIGURE 14. On insertion of the sleeve 3 into body 1 the air pressure built up in the space *b* will force the sides of the cut 5'' upwards and apart to allow said air to escape. On completion of the filling operation the pressure is removed or replaced by a vacuum so that the sides of the cut or cuts will close in again to provide a tightly sealed assembly.

As shown in FIGURES 8, 9 and 12, the body member 1 may desirably be reduced to minimum vertical dimension thereby saving packing material. Such dimension should, however, be large enough to contain the full amount of material which is to be contained in the final packing assembly comprising both members 1 and 3. Reducing the vertical dimension of the body member 1, moreover, has the further advantage of providing a readily grippable portion of sleeve member 3 projecting above the body member 1, to expel the suppository out of the packing in case of a tendency of the suppository to stick to the body member 1. As already noted, expulsion out of the sleeve member 3 is easily effected by finger pressure.

To facilitate opening the package in spite of the relatively tight clamping pressure between the two receptacles, means such as an annular bead 16 (FIGURE 13) or a pair of radial lugs 17 (FIGURE 14) may be provided on the upper end of slaeeve 3. Instead of projecting in the plane of said wall as do the lugs 17 in FIGURE 14, such lugs may be formed to project at an angle, e.g. vertically upward, therefrom; such an arrangement will at the same time further facilitate expulsion of the contents out of the sleeve 3 by finger pressure on the lugs.

As explained in connection with the embodiments first described, packing molds of the kind shown in FIGURES 8 to 14 may be interconnected into bunches, as shown in FIGURE 15, which shows a fragment of such a bunch including two individual packing molds. In the exemplary form shown in FIGURE 15 the individual packing molds are interconnected by strips 12 extending in a common plane extending through the center axes of all the packing molds, each strip portion being formed with a weak or frangible area 12 to facilitate separation. FIGURE 15 also shows the sleeve members 3 interconnected by top strips or flanges 14 extending between and generally coplanar with the top walls of the sleeves and also formed with weak sections 15 aligned with the sections 13.

It will be understood that various features shown and described with reference to different embodiments may be interchanged between such embodiments, and numerous other modifications made without departing from the scope and spirit of the invention.

What I claim is:

1. A packaging and molding unit comprising a main body of stiff polystyrene being opened at one end and having an interior surface which defines a cylinder at said open end and a tapered closed end opposed thereto; an inner sleeve of flexible polyethylene having an interior surface and telescoped to a predetermined depth substan-

tially within the cylinder of said main body, said sleeve closed only at the end opposed to said tapered closed end of said main body to thus seal said main body, the interior surface of said inner sleeve being shaped to define in cooperation with said tapered end a mold cavity having an intermediate diameter larger than the diameter at either end; and a product such as a suppository molded to fill said cavity and removable therefrom in said molded shape on opening said unit, the volume of said main body being at least as great as the volume of said product.

2. A packaging and molding unit comprising a main body being opened at one end and having an interior surface which defines a cylinder at said open end and a tapered closed end opposed thereto; an inner sleeve having an interior surface and telescoped to a predetermined depth substantially within the cylinder of said main body, said sleeve closed only at the end opposed to said main body, the interior surface of said inner sleeve being shaped to define in cooperation with said tapered end a mold cavity having an intermediate diameter larger than the diameter at either end, the diameter of said inner sleeve at its open end being slightly greater than the maximum internal diameter of said main body whereby said sealing of said main body by said sleeve is tight; and a product such as a suppository molded to fill said cavity and removable therefrom in said molded shape on opening said unit, the volume of said main body being at least as great as the volume of said product.

References Cited in the file of this patent

UNITED STATES PATENTS

1,564,310	Jones	Dec. 8, 1925
2,203,421	Stevenson	June 4, 1940
2,219,181	Graham	Oct. 22, 1940
2,612,261	Percopo	Sept. 30, 1952
2,797,805	Berard	July 2, 1957

FOREIGN PATENTS

55,629	France (2nd add. Pat. 848,960)	May 21, 1952
493,134	Belgium	May 2, 1950
734,838	Great Britain	Aug. 10, 1955
1,081,229	France	June 9, 1954
1,096.474	France	Feb. 2, 1955